**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| HUMAN GENOME SCIENCES, INC., | ) | |
| | ) | C.A. NO. 08-166-SLR |
| Plaintiff, | ) | |
| | ) | **PUBLIC VERSION** |
| v. | ) | |
| | ) | |
| GENENTECH, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**DECLARATION OF REBECCA FETT IN SUPPORT OF GENENTECH INC.'S MOTION TO DISMISS**

OF COUNSEL:

WEIL, GOTSHAL & MANGES LLP
Matthew D. Powers
Vernon M. Winters
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802 3000

WEIL, GOTSHAL & MANGES LLP
Elizabeth Stotland Weiswasser
Peter Sandel
Rebecca Fett
767 Fifth Avenue
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Philip A. Rovner (#3215)
POTTER ANDERSON & CORROON LLP
Hercules Plaza
P.O. Box 951
Wilmington, DE 19899
(302) 984-6000
E-mail: provner@potteranderson.com

Attorneys for Defendant
Genentech Inc.

Dated: May 28, 2008

I, Rebecca Fett, declare:

1. I am an associate at Weil, Gotshal & Manges LLP, counsel for defendant Genentech, Inc. ("Genentech") in this action. I make this declaration in support of Genentech's Motion to Dismiss, dated May 28, 2008.

2. Attached hereto as **Exhibit 1** is a true and correct copy of Paper 1 in Interference No. 105,361 ("the '361 Interference").

3. Attached hereto as **Exhibit 2** is a true and correct copy of Paper 23 in the '361 Interference.

4. Attached hereto as **Exhibit 3** is a true and correct copy of Paper 26 in the '361 Interference.

5. Attached hereto as **Exhibit 4** is a true and correct copy of Paper 96 in the '361 Interference.

6. Attached hereto as **Exhibit 5** is a true and correct copy of Paper 107 in the '361 Interference.

7. Attached hereto as **Exhibit 6** is a true and correct copy of Paper 109 in the '361 Interference.

8. Attached hereto as **Exhibit 7** is a true and correct copy of Paper 112 in the '361 Interference.

9. Attached hereto as **Exhibit 8** is a true and correct copy of Paper 113 in the '361 Interference.

10. Attached hereto as **Exhibit 9** is a true and correct copy of Paper 114 in the '361 Interference.

11. Attached hereto as **Exhibit 10 [FILED UNDER SEAL]** is a redacted copy of a letter from the Office Of Enrollment And Discipline Re: File No. C2006-48, dated March 27, 2007.

12. Attached hereto as **Exhibit 11** is a true and correct copy of Paper 39 in the '361 Interference.

13. Attached hereto as **Exhibit 12** is a true and correct copy of Paper 99 in the '361 Interference.

14. Attached hereto as **Exhibit 13** is a true and correct copy of Paper 2 in the '361 Interference.

15. Attached hereto as **Exhibit 14** is a true and correct copy of the Ni Response to Order to Show Cause (without Appendices) in Interference No. 105,381.

16. Attached hereto as **Exhibit 15** is a true and correct copy of Paper 110 in the '361 Interference.

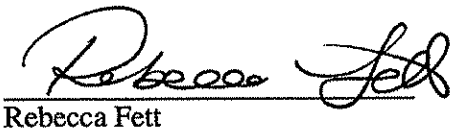
17. Attached hereto as **Exhibit 16 [FILED UNDER SEAL]** is a true and correct copy of a letter from Vernon Winters to Richard DeLucia, dated May 8, 2008.

18. Attached hereto as **Exhibit 17** is a true and correct copy of an email from Richard DeLucia to Elizabeth Stotland Weiswasser, dated May 20, 2008.

19. Attached hereto as **Exhibit 18** is a true and correct copy of HGS's Motion for Reconsideration and Modification of Order, dated May 23, 2008 (Case No. 07-780-SLR, D.I 30).

Executed this 28th day of May, 2008, at New York City, New York.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.



Rebecca Fett

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Philip A. Rovner, hereby certify that on May 28, 2008, the within document was filed with the Clerk of the Court using CM/ECF; that the document was served on the following party as indicated; and that the document is available for viewing and downloading from CM/ECF.

**BY HAND DELIVERY AND E-MAIL**

Steven J. Balick, Esq.
John G. Day, Esq.
Ashby & Geddes LLP
500 Delaware Avenue, 8th Floor
Wilmington, DE 19899
Sbalick@ashby-geddes.com
jday@ashby-geddes.com

I hereby certify that on May 28, 2008 I have sent by E-mail the foregoing document to the following non-registered participants:

Richard L. DeLucia, Esq.
John R. Kenny, Esq.
Kenyon & Kenyon
One Broadway
New York, NY 10004
rdelucia@kenyon.com
jkenny@kenyon.om

/s/ Philip A. Rovner
Philip A. Rovner (#3215)
Potter Anderson & Corroon LLP
Hercules Plaza
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com

# EXHIBIT 1

Paper 1

Filed by: Richard E. Schafer
Administrative Patent Judge
Mail Stop Interference
P.O. Box 1450
Alexandria Va 22313-1450
Tel: 571-272-9797
Fax: 571-273-0042

Filed
August 31, 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).

---

Patent Interference No. 105,361 (RES)

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# DECLARATION

**Part A. Declaration of interference**

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties. Details of the application(s), patent (if any), reissue application (if any), count(s) and claims designated as corresponding or as not corresponding to the count(s) appear in Parts E and F of this DECLARATION.

**Part B. Judge managing the interference**

Administrative Patent Judge Richard E. Schafer has been designated to manage the interference. 37 CFR § 41.104(a) [Bd. R. 104(a)].

**Part C. Standing order**

A Trial Section STANDING ORDER [SO] accompanies this DECLARATION. The STANDING ORDER applies to this interference.

**Part D. Initial conference call**

A telephone conference call to discuss the interference is set for **2:30 p.m. on October 24, 2005** (the Board will initiate the call).

No later than **two business days** prior to the conference call, each party shall file and serve by facsimile (SO ¶ 4.5) a list of the motions (Bd. R. 120; Bd. R. 204; SO ¶ 26) the party intends to file.

**Part E. Identification and order of the parties**

| | Junior Party |
|---|---|
| Named inventors: | Jian Ni, Rockville, MD<br>Reiner L. Gentz, Rockville, MD<br>Guo-Liang Yu, Berkeley, CA<br>Craig A. Rosen, Laytonsville, MD |
| Patent: | 6,872,568, granted March 29, 2005, based on Application 09/565,009, filed May 4, 2000 |
| Title: | Death domain containing receptor 5 antibodies |
| Assignee: | Human Genome Sciences, Inc. |
| Accorded Benefit: | None |
| | Senior Party |
| Named Inventors: | Camellia W. Adams, Mountain View, CA<br>Avi J. Ashkenazi, San Mateo, CA<br>Anan Chuntharapai, Colma, CA<br>Kyung Jin Kim, Los Altos, CA |
| Applicationt: | 10/423,448, filed April 25, 2003 |
| Title: | Apo-2 Receptor Antibodies |
| Assignee: | Genentech, Inc. |
| Accorded Benefit: | Application 10/288,917 filed November 6, 2002<br>Application 10/052,798 filed November 2, 2001<br>Application 09/079,029 filed May 14, 1998 |

The senior party is assigned exhibit numbers 1001-1999. The junior party is assigned exhibit numbers 2001-2999. Bd. R. 154(c)(1). The senior party is responsible for initiating settlement discussions. SO ¶ 18.

**Part F. Count and claims of the parties**

Count 1

Claim 21 of Ni U.S. Patent 6,872,568 or Claim 134 of Adams Application 10/423,448.

The claims of the parties are:

Ni: 1-52

Adams: 114-165

The claims of the parties which correspond to Count 1 are:

Ni: 1-6, 8-19, 21-32, 34-45 and 47-52

Adams: 114-119, 121-132, 134-145, 147-158, 160-165

The claims of the parties which do not correspond to Count 1 are:

Ni: 7, 20, 33, 46

Adams: 120, 133, 146, 159

Count 2

Claim 20 of Ni U.S. Patent 6,872,568 or Claim 133 of Adams Application 10/423,448

The claims of the parties which correspond to Count 2 are:

Ni: 7, 20, 33, 46

Adams: 120, 133, 146, 159

The claims of the parties which do not correspond to Count 2 are:

Ni: 1-6, 8-19, 21-32, 34-45 and 47-52

Adams: 114-119, 121-132, 134-145, 147-158, 160-165

**Part G. Heading to be used on papers**

The heading in SO Form 1 must be used on all papers filed in this interference. SO ¶ 7.2.1. The administrative patent judge and parties must be indicated as follows:

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).

---

Patent Interference No. 105,361 (RES)

---

**Part H. Order form for requesting file copies**

When requesting copies of files, use of SO Form 4 will greatly expedite processing of the request. Please attach a copy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

/ss/ Richard E. Schafer
RICHARD E. SCHAFER
Administrative Patent Judge

Enc:
Copy of STANDING ORDER
Copy U.S. Patent 6,872,568
Copy of claims of Application 10/423,448.

Revised September 2004

cc (via overnight delivery):

Attorney for Human Genome Sciences:

STERNE KESSLER GOLDSTEIN & FOX PLLC
1100 New York Avenue
Suite 600
Washington, DC 20005-3934

Tel: 202-371-2600
Fax: 202-371-2540

Attorney for Genentech:

GENENTECH, INC.
1 DNA Way
South San Francisco, CA 94080

Tel: 650-225-1719
Fax: 650-952-9881

# EXHIBIT 2

Paper 23 mg 10/21/05

Filed on behalf of: Party Ni
By: Jorge A. Goldstein, Esq.
Eldora L. Ellison, Esq.
Sterne, Kessler, Goldstein & Fox, P.L.L.C.
1100 New York Avenue, NW
Washington, D.C. 20005-3934
Tel: (202) 371-2600
Fax: (202) 371-2540

Filed: October 20, 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)



Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).

Patent Interference No. 105,361 (RES)

**NI LIST OF INTENDED MOTIONS**

Patent Interference No. 105,361

MAIL STOP INTERFERENCE
Board of Patent Appeals and Interferences
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA. 22313-1450

Sir:

Pursuant to the Declaration of Interference and Standing Order ¶26, Party Ni hereby provides its list of intended motions to be filed in the above-captioned interference.

1. Pursuant to §41.208(a)(2), a motion seeking to change the scope of the definition of the interfering subject matter by amending the count such that it better encompasses Human Genome Sciences' (HGS) proofs.

2. Pursuant to §41.208(a)(3), a motion seeking to change the benefit accorded for the count.

3. Pursuant to §41.208(a)(3), a motion seeking to change the benefit accorded for the count, which motion is contingent upon changing the scope of the definition of the interfering subject matter by amending the count as outlined above in (1).

4. Pursuant to §41.208(a)(4), a motion seeking judgment on priority.

5. Pursuant to §41.208(a)(4), a motion seeking judgment on priority, which motion is contingent upon changing the scope of the definition of the interfering subject matter by amending the count as outlined above in (1).

6. Pursuant to §41.121(a)(3), a motion seeking to compel testimony of Dr. Vishva M. Dixit under §41.150(c) or §41.156(a).

7. Pursuant to §41.121(a)(3), a motion seeking to compel production from Dr. Vishva M. Dixit under §41.150(c) or §41.156(a).

8. Pursuant to §41.121(a)(3), a motion seeking to compel testimony of Dr. Guohau "James" Pan under §41.156(a) and (b).

9. Pursuant to §41.121(a)(3), a motion seeking to compel production from Dr. Guohau "James" Pan under §41.156(a) and (b).

10. Pursuant to §41.121(a)(3), a motion seeking to compel production from the University of Michigan under §41.156(a).

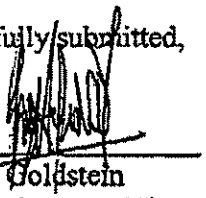
11. Pursuant to §41.121(a)(1)(iii), a motion seeking sanctions against Genentech due to inappropriate conduct in view of §1.99, §1.291, and 35 USC §122(c). The

inappropriate conduct included repeated *ex parte* protests against the validity of any patent that could or may issue from HGS's application No. 09/565,009 (which issued as the involved U.S. Patent No. 6,872,568) or on the basis of HGS's priority application No. 60/040,846. The inappropriate conduct occurred in the prosecution of Genentech's U.S. patent application No. 09/020,746, which application was directed to substantially the same subject matter as the subject matter in the involved Genentech application. The requested sanctions include an award ordering judgment in the interference to HGS.

12. Pursuant to §41.208(a)(1), a motion for unpatentability of all claims of the involved Genentech application No. 10/423,448 as anticipated under 35 U.S.C. §102(e) by HGS's U.S. Patent No. 6,872,568, which claims priority to application No. 60/040,846, filed March 17, 1997.

13. Pursuant to §41.121(a)(3), a motion seeking synchronization of (a) the time periods set in the present interference with (b) the time periods set in interference 105,240, which also involves HGS's U.S. Patent No. 6,872,568. Alternatively, the requested relief includes delaying any disclosure of the nature and contents of the papers filed at each of time periods 1 through 8 in the present interference until such time that each of the corresponding time periods 1 through 8 has passed in interference 105,240, or vice versa.

Respectfully submitted,



Jorge A. Goldstein
Attorney for Party Ni
Registration No. 29,021

Date: October 20, 2005

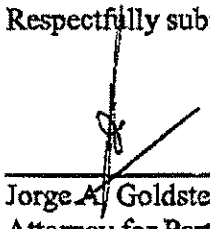
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Washington, D.C. 20005-3934

**CERTIFICATE OF SERVICE**

I, Jorge A. Goldstein, hereby certify that a copy of the foregoing NI LIST OF INTENDED MOTIONS, filed October 20, 2005, has been served on the attorney of record of Party Adams via facsimile on this 20th day of October, 2005, addressed as follows:

Oliver R. Ashe, Jr.
Greenblum & Bernstein, PLC
1950 Roland Clarke Place
Reston, VA 20191
Tel: 703-716-1191
Fax: 703-716-1180

Respectfully submitted,



Jorge A. Goldstein
Attorney for Party Ni
Registration No. 29,021

Date: October 20, 2005

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Washington, D.C. 20005-3934

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

# Fax

☒ Urgent ☐ Return reply requested ☐ Original will be sent as confirmation

To: **USPTO/BPAI**

Date: October 20, 2005

Attention: Judge Richard E. Schafer

Re: **Human Genome Sciences, Inc. v. Genentech, Inc.**
**Patent Interference No. 105,361 (RES)**

From: Jorge A. Goldstein, Esq.

Pages (including cover sheet): 5

Your Reference: 105,361 (RES)

Fax No: 571.273.0042

Our Reference: 1488.1311FR6

# Message

Certificate of Facsimile Transmission
I hereby certify that this paper is being facsimile transmitted to the Board of Patent Appeals and Interferences on the date shown below.

Kim R. Perry

Date: October 20, 2005

456538_1.DOC

If any portion of this transmission is not received clearly or in full, contact us at 202.371.2600 or f 202.371.2540

# EXHIBIT 3

Paper 26
Filed: October 25, 2005

Mail Stop Interference
P.O. Box 1450
Alexandria Va 22313-1450
Tel: 571-272-9797
Fax: 571-273-0042

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).

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Patent Interference No. 105,361 (RES)

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**Order - Miscellaneous - Bd.R. 104(a)**

SCHAFER, Administrative Patent Judge.

**A. Conference call**

A telephone conference call was held on October 24, 2005 at approximately 2:30 p.m., involving:

1. Jorge A. Goldstein, Esq., counsel for Human Genome Sciences (HGS),
2 Oliver R. Ashe, Jr. , counsel for Genentech, and
3. Richard E. Schafer, Administrative Patent Judge.

**B. Relevant discussion during conference call**

The principal purpose of the conference call was to discuss the motions the parties desired to file during the first phase of the interference. The parties should note the additional provisions set forth in the Appendix to this order.

Genentech sought to authorization to file the following motions (Paper 24):

1. A motion to designate certain claims of both parties as corresponding to Count 2;
2. A contingent motion for the benefit of provisional Application 60/074,119 and a contingent motion for the benefit of Application 60/046,615 contingent on the grant of a motion for benefit filed by HGS;
3. A motion for judgment based upon priority; and
4. A number of miscellaneous motions relating to Interference 105,240.

During the conference call Genentech was authorized to file the motion to designate claims and a single contingent motion for benefit addressing the benefit of both provisional applications. The motion for priority will be taken up in the second phase of the interference and is therefore deferred. The miscellaneous motions relating to Interference 105,240 were not authorized. The matters sought to be considered by the miscellaneous motions will be evaluated as the motions phase of this interference and Interference 105,240 progresses.

HGS sought authorization for filing the following motions:

1. A motion to change the scope of the count;
2. A motion for benefit as to the current counts and a motion, contingent on the grant of the motion to change the counts, for benefit as to the amended counts;
3. Motions for priority based upon the count or amended counts;

4. Motions seeking discovery of testimony of and production of documents from certain individuals and production of documents from the University of Michigan;
5. A miscellaneous motion for sanctions against Genentech for alleged misconduct in interfering with the ex parte prosecution of HGS's application which matured into its involved patent;
6. A motion for unpatentability of Genentech's involved claims asserting unpatentability over HGS's involved patent; and
7. A motion to synchronize the time periods set in this interference and those set in 105,240.

The motion to change the scope of the count was authorized. The motion and contingent motions were authorized to be filed as a single motion. The motions for priority were not authorized and are deferred to the second phase of the interference. A single motion for discovery was authorized to be filed within 10 days (**Thursday, November 3, 2005**). An opposition was authorized to be filed within 10 days of the service of the motion. The motion for sanctions was authorized. The motion for unpatentability over HGS's involved patent was not authorized. The filing of the motion to synchronize the times of this interference and Interference 105,240 was authorized to be filed by **Friday, October 28, 2005.** No opposition was authorized at this time.

The times set herein may be modified by mutual consent of the parties provided a notice of the modification is promptly filed. The times set in the order entered August 31, 2005(Paper 4), remain in effect.

/ss/ Richard E. Schafer
Richard E. Schafer
Administrative Patent Judge

cc (FAX):

Attorney for Human Genome Sciences:

Jorge A. Goldstein, Esq
STERNE KESSLER GOLDSTEIN & FOX PLLC
1100 New York Avenue
Suite 600
Washington, DC 20005-3934

Tel: 202-371-2600
Fax: 202-371-2540

Attorney for Genentech:

Oliver R. Ashe, Jr. Esq.
GREENBLUM & BERNSTEIN, PLC
1950 Roland Clarke Place
Reston, VA 20191

Tel: 703-716-1191
Fax: 703-716-1180

**Appendix**
**(Times for substantive motions; priority deferred)**

Interference 105,361 (RES)

## I. Required Appendices

### 1. List of exhibits

The list of exhibits cited in support of a motion, opposition, or reply, SO ¶¶ 13.3(b) & 14.3(a), must be set forth as an appendix to the motion, opposition, or reply, respectively. The appendix will not count against the page limit for the motion, SO ¶ 13.2, or opposition or reply, SO ¶ 14.2.

### 2. Statement of Material Facts

The statement of material facts for each motion, opposition, or reply must be set forth as an appendix to the motion, opposition, or reply, respectively. Bd. R. 121(d)(2). The appendix will not count against the page limit for the motion, SO ¶ 13.2, or opposition or reply, SO ¶ 14.2.

# EXHIBIT 4

Paper 96
Filed: August 22, 2006

Mail Stop Interference
P.O. Box 1450
Alexandria Va 22313-1450
Tel: 571-272-4683
Fax: 571-273-0042

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).

---

Patent Interference No. 105,361 (RES)

---

Before: SCHAFER, HANLON and SPIEGEL, Administrative Patent Judges.

SCHAFER, Administrative Patent Judge.

**Decision - Interlocutory Motions - Bd.R. 125(b)**

Human Genome Sciences (HGS) moves for sanctions against Genentech because of alleged interference with the ex parte examination of HGS' application which matured into HGS' involved patent. Paper 39. HGS has also submitted a complaint (Ex. 2050) to the USPTO's Office of Enrollment and Discipline (OED). We dismiss the motion since OED is better suited to addressing matters of potential attorney misconduct occurring during ex parte examination.

HGS argues that certain activities by Genentech during the prosecution of Genentech's Application 09/020,746 were inappropriate and unauthorized protests against the patentability of the claims of HGS' Application 09/565,009 which issued as HGS' involved patent. The inappropriate activities relate to the filing of certain declarations which, in HGS' view, were "all out attacks on the enablement, written description and utility disclosures" of certain applications, the filing dates of which HGS claimed benefit, and HGS' 009 application. Paper 39, p. 4. HGS relies on parts of the prosecution history of Genentech's 746 application for support. For example, HGS relies on a statement made by Genetech's counsel in Genentech's 746 application asserting that the claims of HGS' 009 application were not patentable:

> [Genentech] also observes that in at least two previous communications to the Office during the prosecution of the instant application (e.g., two Supplemental Responses filed on 1/22/03 and 2/28/03), [Genentech] provided information and evidence that [HGS] '009 application (or a patent that issues therefrom) cannot be prior art to the instant application and cannot support a claim to subject matter presently claimed in this application. For example, [Genentech] submitted a §1.131 declaration on 2/28/03 that antedates the earliest filing date claimed by [HGS] '009 application, i.e., March 17, 1997. Because of this, [Genentech] believes that any patent that could or may issue from [HGS]'009 application would not be valid.

Ex. 2045, pp. 3-4, bracketing substituting (1) "Genentech" for "Applicant" and (2) "HGS" for "the" before each reference to the 009 application and underlining added.

In addition to filing a motion for sanctions, HGS states that it has also filed a complaint with the USPTO's Office of Enrollment and Discipline. Paper 39, p. 19. That Office has been delegated the authority to investigate and enforce the rules of conduct applicable to all those who represent applicants before the USPTO.

Assuming, without deciding, the truth of the allegations made by HGS, the matters alleged appear to be attorney conduct matters which do not impact the patentability of either HGS' involved patent or Genentech's involved application. We conclude, therefore, that OED is in the best position to address the issues raised. They have the necessary tools to review and investigate fully HGS' allegations.

HGS Substantive Motion 5 (Paper 39) is dismissed.

/Richard E. Schafer/
RICHARD E. SCHAFER
Administrative Patent Judge

/Adriene Lepiane Hanlon/
ADRIENE LEPIANE HANLON
Administrative Patent Judge

/Carol A. Spiegel/
CAROL A. SPIEGEL
Administrative Patent Judge

) BOARD OF PATENT APPEALS AND INTERFERENCES

cc (facsimile):

Counsel for Human Genome Sciences:

Jorge A. Goldstein, Esq
STERNE KESSLER GOLDSTEIN & FOX PLLC
1100 New York Avenue
Suite 600
Washington, DC 20005-3934
Tel: 202-371-2600
Fax: 202-371-2540

Counsel for IMMUNEX CORPORATION:

Michael J. Wise, Esq.
PERKINS COIE LLP
1620 26 Street, 6 Floor, South Tower
Santa Monica, CA 90404-4013
Tel: 310-788-3210
Fax: 310-788-3399

# EXHIBIT 5

Paper: 107
Filed: 28 November 2007

Mail Stop Interference
P.O. Box 1450
Alexandria VA 22313-1450
Tel: 571-272-4683
Fax: 571-273-0042

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568),

v.

Genentech, Inc.
Senior Party
(Application 10/423,448).

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Patent Interference No. 105,361 (RES)

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*Before*: RICHARD E. SCHAFER, MICHAEL P. TIERNEY and JAMES T. MOORE[1], *Administrative Patent Judges*.

MOORE, *Administrative Patent Judge*.

**DECISION ON MOTIONS**

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[1] Judge Moore is substituting for Judge Spiegel. See In re Bose Corp., 772 F.2d 866, 227 USPQ 1, 2-4 (Fed. Cir. 1985).

## A. Introduction

This interference was declared August 31, 2005, with Human Genome Sciences, Inc. (hereinafter "HGS") as the junior party to Genentech, Inc. (hereinafter "Genentech"). (Paper 1, page 2). HGS therefore bears the ultimate burden of proving priority in this interference.

### 1. The Interfering Subject Matter

The subject matter of the present interference includes antibodies which bind with a protein called a cell death receptor. More particularly, count 1 deals with so-called "antagonist" monoclonal antibodies and count 2 deals with so-called "agonist" monoclonal antibodies of this receptor. Antagonists compete for a receptor binding site and inhibit a response, while agonists bind to a receptor and trigger a response. In this instance, the antibodies work in the so-called "death domain" receptors which trigger (or prevent triggering of) apoptosis, or cell death.

### 2. Procedural Posture of the Case

The motions of record are as follows:

HGS/Ni Miscellaneous Motion 1 (October 31, 2005) (Paper 27) to synchronize interferences 105,240 and 105,361. APJ Schafer granted this motion November 15, 2005 in Paper 34.

HGS/Ni Miscellaneous Motion 2 (November 4, 2005) (Paper 31) to compel testimony and the production of documents, and to grant additional discovery. APJ Schafer denied this motion January 12, 2006 in Paper 51. Unsatisfied, HGS/Ni filed a request for rehearing of the decision on January 27, 2006 (Paper 53). That request for rehearing is pending and decided herein.

HGS/Ni Substantive Motion 3 (December 8, 2005) (Paper 37) to change benefit.

HGS/Ni Substantive Motion 4 (December 8, 2005) (Paper 38) to substitute new counts 3 and 4.

HGS/Ni Substantive Motion 5 (December 8, 2005) (Paper 39) for sanctions. A panel of Judges Schafer, Hanlon, and Spiegel denied this motion August 22, 2006. (Paper 96).

HGS/Ni Miscellaneous Motion 6 (April 27, 2006) (Paper 75) for permission to file a supplemental opposition to Genentech/Adams Motion 2 for benefit of earlier filed applications. APJ Schafer denied this motion May 2, 2006 (Paper 77).

HGS/Ni Motion 7 to exclude evidence. (May 4, 2006) (Paper 78).

Genentech/Adams Substantive Motion 1 (December 8, 2005) (Paper 42) to designate claims as corresponding to the count.

Genentech/Adams Substantive Motion 2 (December 8, 2005) (Paper 43) for benefit of earlier filed applications.

Genentech/Adams Responsive Motion 3 (January 5, 2006) (Paper 48) for benefit of earlier filed applications.

Oral argument was heard on July 27, 2006 at the Board of Patent Appeals and Interferences before a panel consisting of Administrative Judges Schafer, Spiegel, and Tierney. A revised copy of the transcript is of record (Paper 99) along with the original (Paper 97).

**B. General Findings of Fact**

I. The Interference

001. The first part of the interfering subject matter is designated "Count 1" and includes Claim 21 of HGS 6,872,568 ('568) or Claim 134 of Genentech 10/423,448 ('448). (Paper 1).

002. HGS '568 Claim 15 reads as follows:

> 15. An isolated monoclonal antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 1 to 133 of SEQ ID NO:2.

003. HGS '568 Claim 21 reads as follows:

> 21. The antibody or fragment thereof of claim 15 wherein said antibody or fragment thereof is an antagonist of the protein of SEQ ID NO:2.

004. HGS's portion of Count 1 can be summed up as an antibody or fragment which is an antagonist of the 133 sequence protein of SEQ ID NO:2.

005. The other alternative of Count 1 is claim 134 of Genentech's '448 application, which reads as follows, is much like HGS':

> 134. The antibody of fragment thereof of claim 128 wherein said antibody or fragment thereof is an antagonist of the protein of SEQ ID NO:1.

006. Claim 128 reads as follows:

> 128. An isolated monoclonal antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 52 to 184 of SEQ ID NO:1.

007. It is not in dispute that amino acid residues 52-184 of Genentech '448 SEQ ID NO:1 are identical to amino acid residues 1-133 of HGS '568.

008. HGS and Genentech are claiming the same "stuff" in Count 1.

009. The second part of the interfering subject matter is designated "Count 2" and includes Claim 20 of HGS 6,872,568 ('568) or Claim 133 of Genentech 10/423,448 ('448). (Paper 1).

010. Count 2 is Claim 20 of HGS '568 or Claim 133 of Genentech '448, and relate to the agonist of the protein.

011. Claim 20 of HGS '568 reads as follows:

> 20. The antibody or fragment thereof of claim 15 wherein said antibody or fragment thereof is an agonist of the protein of SEQ ID NO:2

012. Claim 133 of Genentech '448 reads as follows:

> 133. The antibody or fragment thereof of claim 128 wherein said antibody or fragment thereof is an agonist of the protein of SEQ ID NO:1.

013. Claim 20 of HGS and Claim 133 of Genentech are directed to the same material.

014. The interference involves junior party HGS versus senior party Genentech.

015. HGS is involved on the basis of U.S. Patent 6,872,568 B1, issued 29 March 2005, based on application 09/565,009, filed 4 May 2000. Ex. 2004.

016. Genentech is involved on the basis of application 10/423,448, filed 25 April 2003. Ex. 1044.

017. Genentech has been accorded an earliest constructive reduction to practice, i.e., benefit for the purpose of priority of application 09/079,029, filed 14 May 1998. Paper 1, page 2.

018. HGS is junior party because its earliest constructive reduction to practice of 4 May 2000 is later than the constructive reduction to practice accorded to Genentech/Adams of 14 May 1998.

II. Claims Corresponding to the Counts

019. HGS/Ni's patent contains claims 1-52, but only claims 1-6, 8-19, 21-32, 34-45, and 47-52 have been designated as corresponding to Count 1.

020. HGS/Ni's claims 7, 20, 33, and 46 have been designated as corresponding to Count 2.

021. Genentech/Adams' application contains claims 114-165, but only claims 114-119, 121-132, 134-145, 147-158, and 160-165 have been designated as corresponding to Count 1.

022. Genentech/Adams' claims 120, 133, 146, and 159 have been designated as corresponding to Count 2.

023. There are no claims of either party which do not correspond to Count 1 or Count 2.

**C. (I) HGS Motion 4 - To Substitute Proposed Counts 3 and 4 and (II) Adams Responsive Motion 3 - For benefit to the Substitute Counts 3 and 4**

HGS/Ni seeks to substitute counts 3 and 4 for counts 1 and 2 in this interference, by deleting the limitation of "monoclonal" from the counts.

1. Specific Findings of Fact

024. HGS/Ni proposed count 3 reads as follows:

An isolated ~~monoclonal~~ antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 1 to 133 of SEQ ID NO:2 [of Patent 6,872,568], wherein the antibody or fragment thereof is an antagonist of the protein of SEQ ID NO:2,

Or

Claim 134 of Adams Application 10/423,448. (strikeout indicates material HGS desires removed from present count, brackets added by this opinion).

025. HGS/Ni proposed count 4 reads as follows:

An isolated ~~monoclonal~~ antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 1 to 133 of SEQ ID NO:2 [of Patent 6,872,568], wherein the antibody or fragment thereof is an agonist of the protein of SEQ ID NO:2,

Or

Claim 133 of Adams Application 10/423,448. (strikeout indicates removed from present count, brackets added by this opinion).

2. Legal Standard

A count is a description of the interfering subject matter that sets the scope of admissible proofs on priority. Bd. R. 201.

A party seeking to change the count in an interference must demonstrate a genuine need to change the count. *Louis v. Okada*, 59 USPQ2d 1073, 1076 (Bd. Pat. App. & Int. 2001).

As the moving party, HGS/Ni bears the burden of proof. Bd.R. 41.121(b).

3. Discussion

HGS moves to delete the term "monoclonal" from each of counts one and two. HGS tells us that its best proofs for conception, which it regards as documentary proofs, are outside the scope of the counts. (Paper 38, page 3, last paragraph).

A party attempting to establish a genuine need to change the count needs to establish several points to be persuasive. Foremost, however, the party seeking to change the count must show through a proffer that the proofs at issue fall outside the scope of the present count. Otherwise, the whole exercise is merely academic in nature.

HGS proffers three written documents A, B, and C as its "best proofs."

We initially note that HGS appears to misapprehend the meaning of "best proofs." Best is not an evidentiary term relating to the type of evidence such as documentary or oral testimony; rather, the "best proof" is the best case the party can put on for purposes of proving priority. This is a

substantive judgment as to the best case - for example, choosing the earliest experiment which can be proven. That experiment must fall within the scope of the count to be probative as to priority.

Proving the best case ("best proofs") can be established a number of ways, by documents, by testimony explaining the significance of the documents, and by effective argument utilizing this evidence. A "best proof" is not what a single document shows standing alone.

We now turn to HGS/Ni's arguments.

Document A is said to be a project report showing Jian Ni (an inventor) identified a clone containing a nucleic acid of a novel TNFR, designated TR7. The document is said not to recite antibodies or monoclonal antibodies. (Paper 38, paragraph bridging pages 4 and 5).

The fact that the document did not recite antibodies or monoclonal antibodies is not dispositive. The question is whether this document in the case in its entirety establishes a conception which is within the scope of the count. All HGS has done is to point to a deficiency in this specific piece evidence, but has not shown that its proofs as a whole, including this document, are outside the scope of the present count.

Document B is said to be an email from Jian Ni describing discovery of a novel TNFR-like gene. Again, HGS states that the document does not expressly recite antibodies or monoclonal antibodies. (Paper 38, page 5, first full paragraph).

This argument misses the point - the question is what case does the document help establish as the party's best proof of conception. Again, all HGS has done is point out a deficiency in this piece of evidence, not how the proof as a whole falls outside the scope of the count.

Document C is said to be a document describing a meeting among scientists including inventors during which raising antibodies against TNF receptors was discussed. HGS states that the document does not expressly mention the TR7 (DR-5) receptor (which is the sequence of interest) or monoclonal antibodies. (Paper 38, page 5, second full paragraph).

However, the specific deficiencies of this piece of proffered evidence do not go to whether the entire proof of their case as a whole is substantively outside of the scope of the count.

HGS seems to urge that each individual piece of its documentary evidence must explicitly recite every element of either count on its own. (Paper 38, Page 6, last two lines.) This interpretation of "best proofs" is incorrect.

In order to show its best proofs are outside the scope of a count, a party need establish what its case is. HGS has not established what its proofs will be and how they relate to the present count. Accordingly, it has not carried the burden to show that these proofs are outside the scope of the count.

HGS Motion 4 to substitute new counts is DENIED.

Genentech Responsive Motion 3 for benefit for the substitute counts, which was responsive to HGS Motion 4, is DISMISSED as moot.

**D. Genentech Motion 1 - to Designate Claims as Corresponding To the Count**

Genentech Motion 1 is a motion to have claims 1-6, 9-19, 22-32, 35-45, and 48-52 of HGS '568 and claims 114-119, 122-132, 135-145, 148-158, 161-165 of Genentech '448 designated as corresponding to count 2. These are termed the "claims at issue" hereafter.

1. Specific Findings of Fact

026. Count 2, inserting appropriate claim language from parent claims, reads as follows:

An isolated monoclonal antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 1 to 133 of SEQ ID NO:2., wherein said antibody or fragment thereof is an antagonist of the protein of SEQ ID NO:2

Or

An isolated monoclonal antibody or fragment thereof that specifically binds to a protein consisting of amino acid residues 52 to 184 of SEQ ID NO:1., wherein said antibody or fragment thereof is an agonist of the protein of SEQ ID NO:1.

027. Amino acid residues 1 to 133 of SEQ ID NO: 2 of HGS/Ni's '568 and amino acid residues 52 to 184 of SEQ ID NO: 1 of Genentech/Adams' '448 are the same.

028. The claims of the parties which correspond to Count 1 are:

HGS/Ni: 1-6, 8-19, 21-32, 34-45 and 47-52

Genentech/Adams: 114-119, 121-132, 134-145, 147-158, 160-165. (Paper 1, page 3).

029. The claims of the parties which correspond to Count 2 are:

HGS/Ni: 7, 20, 33, 46

Genentech/Adams: 120, 133, 146, 159. (Paper 1, page 3).

030. No claims correspond to both counts.

2. The Movant's Burden

A claim corresponds to the count if the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claims. Bd. R. 201.

As the moving party, Genentech/Adams bears the burden of proof. Bd.R. 41.121(b).

3. Discussion

The subject matter of count 1 is directed to antagonist antibodies which bind to the protein, while the subject matter of count 2 is directed to agonist antibodies which bind to the protein. The Declaration set out a rebuttable presumption of claim correspondence for each count.

Genentech/Adams urges, essentially, that because the claims at issue correspond to Count 1, and are not limited to agonist or antagonist antibodies they must, as a matter of law, correspond to Count 2.

Specifically, Genentech/Adams urges that "the subject matter of Count 1, treated as prior art, would have anticipated or rendered obvious the subject matter of the Antagonist Claims and the Claims at Issue. Therefore, as a matter of law, the Antagonist Claims defining Count 1 presumably would have anticipated or rendered obvious the subject matter of the Antagonist Claims and the Claims at issue." (Paper 42, paragraph spanning pages 3 and 4).

Genentech/Adams then goes on to conclude:

"To the extent the Claims at Issue are properly designated as corresponding to Count 1, the Claims at Issue should be designated as corresponding to Count 2. In other words, for the purpose of determining correspondence of the Claims at Issue according to 37 C.F.R. §41.207(b)(2), the Antagonist Claims defining Count 1 would have the same prior art effect as the Agonist Claims defining Count 2. Therefore, the Claims at Issue should correspond to Count 2 because the subject matter of Count 2, treated as prior art, would have anticipated or rendered obvious the subject matter of the Claims at Issue." (Paper 42, page 4).

None of this discussion is evidence that the Claims at Issue are anticipated or rendered obvious by Count 2. Genentech has not established that the Claims at Issue are anticipated by the Count. Genentech has not attempted to do so. Genentech has put no persuasive evidence in the record, only a copy of the Declaration and the parties' clean copies of claims. (Paper 42, Appendix A). The presumption established by the declaration as to Count 1 does not extend to Count 2 and does not relieve Genentech of its burden of showing that the agonist claims also should correspond to Count 2.

Accordingly, Genentech Motion 1 is DENIED. We need not reach, and have not considered the opposition or reply for Genentech Motion 1.

**E. HGS Motion 3 for Benefit**

HGS seeks benefit of several provisional and one non-provisional application for Counts 1 and 2 and proposed Counts 3 and 4. As the motion to substitute proposed Counts 3 and 4 has been denied, this motion is dismissed as moot as to those counts.

HGS/Ni seeks benefit for the following specific applications:

(1) Provisional 60/040,846, filed March 17, 1997

(2) Provisional 60/054,021, filed July 29, 1997

(3) Nonprovisional 09/042,583, filed March 17, 1998

(4) Provisional 60/132,498, filed May 4, 1999

(5) Provisional 60/133,238, filed May 7, 1999, and

(6) Provisional 60/148,939, filed August 13, 1999.

1. Specific Findings of Fact

031. The '846 application was filed 17 March 1997 (NX 2062, cover sheet).

032. Figure 1 of the '846 application is said to show the nucleotide and deduced amino acid sequences of DR5 obtained from the cDNA clone deposited as ATCC Deposit No. 97920 on 7 March 1997 (NX 2062, p. 1, ll. 5-6; 3, ll. 22-25; p. 5, ll. 24-27).

033. According to the '846 specification, DR5 is a 411 amino acid protein (id., p. 6, ll. 25-27).

034. Figure 2 of the '846 application is said to compare the deduced amino acid sequence of DR5 to the amino acid sequences of human tumor necrosis factor 1, human Fas protein and DR3 protein (id., p. 5, ll. 8-13).

2. The Movant's Burden

In order to be entitled to benefit to an application for purpose of a count, the movant must show that the application provides a constructive reduction to practice of the invention under 35 U.S.C. §102(g). More specifically, the application must adequately describe an enabled anticipation of the subject matter of the count. 37 C.F.R. §41.201.

It is "not a question of whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure . . . Rather, it is a question whether the application necessarily discloses that particular device." *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987)

As the moving party, HGS bears the burden of proof. Bd.R. 41.121(b).

3. Discussion

HGS has provided no separate argument for Nonprovisional 09/042,583, filed March 17, 1998; Provisional 60/132,498, filed May 4, 1999; Provisional 60/133,238, filed May 7, 1999, and Provisional 60/148,939, filed August 13, 1999. HGS/Ni is solely relying on Provisional 60/040,846, filed March 17, 1997, and Provisional 60/054,021, filed July 29,

1997. We therefore focus our analysis on those two applications.

Initially, we note that in motion 3, HGS urges that the Examiner's findings should be persuasive. (Paper 37, page 2, ll. 2-5, see also pages 17, 18, 25, and Fact 2). While HGS may reference and rely upon the underlying **factual** basis for the Examiner's decision, that decision itself is not binding or even persuasive as to HGS burden in this interference. In ex-parte prosecution an Examiner has a burden to show unpatentability, absent which the applicant has no burden whatsoever. In interference there are clearly established burdens on a junior and a moving party. There is also an adverse party with competing interests. In sum, these are completely different animals.

Second, we note that there is no clear and direct comparison of the elements of Count 1 or Count 2 to the disclosures of any of the cited applications. This is the pivotal issue involved in any motion for benefit, so the absence of any direct comparison significantly disadvantages the movant. The panel will not make out the movant's case for it by rooting through reams of testimony for the elements of the count.

HGS' summary of its argument is as follows:

> As explained in detail below, HGS's March 17, 1997 priority application , *inter alia,* (i) provides the complete amino acid sequence of DR5 (SEQ ID NO:2), (ii) identifies the amino acid residues that correspond to the ECD of DR5, (iii) recognizes that, because of the sequence similarity between DR5 and other death receptors, DR5 is also a death receptor, (iv) teaches methods for cloning, expressing, and isolating DR5 and portions thereof (including the extracellular domain), (v) teaches methods for making and using agonistic and antagonistic antibodies (*e.g.*, monoclonal antibodies) that specifically bind to the extracellular domain of DR5, (vi) teaches methods for confirming that antibodies that specifically bind to the extracellular

> domain of DR5 are agonists or antagonists of DR5, and (vii) provides clear and practical uses for such antibodies. (Paper 37, paragraph spanning pages 2 and 3).

The elements of Count 1 and 2 which need to be proven by HGS are as follows:

(1) An isolated monoclonal antibody or fragment thereof

(2) that specifically binds to a protein consisting of amino acid residues 1 to 133 of SEQ ID NO:2. or 52 to 184 of SEQ ID NO:1,

(3) wherein said antibody or fragment thereof is an agonist (for Count 1) or antagonist (for Count 2) of the protein of SEQ ID NO:2 or SEQ ID NO:1.

To expressly meet the limits of the count, one would have to show possession of the antibody which triggered the cell death receptor, as an agonist on the one hand, and an antagonist on the other, isolated and raised from a single cloned source.

We observe that, although not a requirement to show benefit, the movant has not asserted that the antibody was actually made. Nowhere in Paper 37 are we directed to any experimental protocol, trial, or description which shows HGS made or specifically described the isolated monoclonal antibody of the count.

HGS' argument principally relates to enablement, what HGS' expert witness thinks one of ordinary skill in the art "could have" done, not what the application necessarily describes.

For example:

> "As confirmed by the Declaration of Dr. Reed, the DR5 cDNA described in the March 17, 1997 priority application **could have been used** to express the extracellular domain of DR5 in various expression systems. (Fact 28)." (Paper 37, page 9)(emphasis added).

> "According to Dr. Reed, based on the description in HGS's March 17, 1997 application and knowledge in the art by March 17, 1997, expression of the extracellular domain of DR5 for the purposes of creating a purified protein for antibody production **would have been routine** to one of ordinary skill in the art. (Fact 31)." (Paper 37, page 10)(emphasis added)
>
> "In addition, Dr. Reed notes that, by using techniques that were routine by March 17, 1997, **one of ordinary skill in the art could have purified** the expressed DR5 polypeptide (or a fragment thereof) without undue experimentation. (Fact 32)." (Paper 37, page 10).

None of these types of statements supports what the application *does* describe and what the applicant possessed at the time of the filing of the application.

We turn to HGS' specific contentions about the '846 application

HGS urges that the March 17, 1997 application provides the complete sequence of DR5, including the portion of the sequence corresponding to the extracellular domain (amino acids 1-133) as recited in the counts. (Paper 37, page 18, lines 3-4).

We observe that the '846 application does disclose that:

> The present inventors have discovered that the DR5 polypeptide is a 411 residue protein exhibiting three main structural domains. First, the ligand binding domain was identified within residue from about 52 to about 184 in FIG. 1 (SEQ ID NO:2). (X2062, p. 23, ll. 19-22).

As a consequence, we agree with HGS that the naked sequence of the protein enumerated in the counts was in the possession of HGS along with recognition of its three main structural domains.

HGS asserts that possession of the protein includes possession of the antibodies, relying on Federal Circuit dicta found in *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir 2004).

> Therefore, based on our past precedent, as long as an applicant has disclosed a "*fully characterized antigen,*" either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Not cited by HGS, but on the same page of the *Noelle* decision is the following caution, quoted from, 1562 (Fed. Cir. 2000).

> It should be noted, however, that this court in *Vas-Cath* warned that each case involving the issue of written description, "must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited." *Vas-Cath*, 935 F.2d at 1562 (quoting *In re Driscoll*, 562 F.2d 1245, 1250 (C.C.P.A. 1977).

In this case, we heed the Federal Circuit's warning. In the case at hand, the count does not merely recite a binding affinity. Rather, the count has certain functional qualities which must also be established in order for the movant to be accorded benefit – the isolated monoclonal antibodies must be either antagonist or agonist of the specific protein.

According to HGS, according to their expert witness, Dr. Reed, the March 17, 1997 "application provides a clear description of agonistic and antagonistic monoclonal antibodies that bind to the ECD [extracellular domain] of DR5 [the protein sequence in question]. (Fact 59)." (Paper 37, page 19, ll. 8-9).

Fact 59 reads as follows:

> 59. It is noted in the Declaration of Dr. John Reed that the March 17, 1997 priority application provides a clear description of agonistic and antagonistic monoclonal antibodies that bind to the ECD of DR5. (Exhibit 2064, paragraph 48).

Following the thread, we turn to Dr. Reed's declaration, paragraph 48, which states:

> 48. Additionally, I have been informed that a patent application is not required to include a demonstration that an invention has actually been made in order for the application to include an adequate description of such an invention. Ni's March 17, 1997 application provides a clear description of polyclonal antibodies and agonist and antagonist monoclonal antibodies that bind to the ECD of DR5. For example, **by providing the amino acid sequence of the ECD of DR5, along with methods for producing and screening agonist and antagonist antibodies, Ni's March 17, 1997** application clearly sets forth the applicants' invention. Indeed, Ni's application provides sufficient detail regarding such agonist and antagonist antibodies that a person of ordinary skill in the art could distinguish such antibodies from other agonist and antagonist monoclonal antibodies. Accordingly, Ni's March 17, 1997 application clearly conveys to a person of ordinary skill in the art that the inventors had described monoclonal agonist and antagonist antibodies that specifically bind to the ECD of DR5, and that the inventors recognized that they had described such antibodies. Similarly, Ni's March 17, 1997 application clearly conveys to one of ordinary skill in the art that the inventors had described polyclonal antibodies that bind to the ECD of DR5. (Exhibit 2064, paragraph 48).

The only sentence in the above quoted paragraph which directly references the evidence is bolded above. Every other sentence appears to us to be conclusory in nature. HGS' position is in reality quite simple – the application describes the amino acid sequence of the ECD of DR5, it also references known methods of screening for antibodies, therefore it described the invention.

We are not persuaded by this position. In order to be accorded benefit, the application must adequately describe an enabled anticipation of the subject matter of the count. 37 C.F.R. § 41.201. In addition to requiring adequate written support indicating possession of the invention, it is well established that the invention must be enabled.

The enablement requirement ensures that "that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it." *In re Gay*, 309 F.2d 769, 772 (CCPA 1962). The enablement requirement of 35 U.S.C. §112, first paragraph, also requires that the patent specification enable those skilled in the art how to make and use the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk. A/S*, 108 F.3d 1361, 1365, 42 USPQ2d at 1004 (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

Whether making or using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See *In re Wands*, 858 F.2d 731, 735-737, 8 USPQ2d 1400, 1402-1404 (Fed. Cir. 1988).

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the Board in *Ex parte Formal*, [230 USPQ 546, 547 (Bd. Pat. App. Int. 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (*Id.*)

It is well established that "the scope of enablement … varies inversely with the degree of unpredictability of the factors involved" and

physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Dr. Reed's Testimony

Dr. Reed is unquestionably an expert in the field. (Exhibit 2064, paragraphs 1-13). We understand him to be a frequent expert witness and amply published. Dr' Reed's "story" is as follows.

HGS's '846 application of March 17, 1997 discloses nucleic acid and amino acid sequences of DR5-encoding CDNA and the DR5 protein, and comments on anticipated uses of Dr5, including the production of agonistic and antagonistic monoclonal antibodies and their use in treating disease. (Exhibit 2064, paragraph 15).

HGS's '846 application discloses that DR5 is a member of the TNF Receptor family of receptors. (Exhibit 2064, paragraph 26). DR5 has all of the features of a "classical" TNF-family death receptor, including a leader, an extracellular domain, a transmembrane domain, and an intracellular domain including a death domain. (Exhibit 2064, paragraph 28).

There is "significant" (22-35%) amino acid sequence identity in the cysteine rich domains of DR5 (Exhibit 2064, paragraph 30), which target the protein for display or secretion (Exhibit 2064, paragraph 19). This renders them recognizable as being similar to other well-known death receptors. (Exhibit 2064, paragraph 30). The "death domain" of the deduced DR5 protein is similarly (21-33%) close to other known death receptors. (Exhibit 2064, paragraph 31).

Because of this similarity, "the most reasonable conclusion to draw from Ni's March 17, 1997 application is that DR5 is expected, by persons of ordinary skill in the art, to be a novel death receptor" (Exhibit 2064, paragraph 32).

Genentech, on the other hand, argues that Dr. Reed has not always felt this way. Indeed, they note (Paper 60, FF 277, page B-34) that he recently stated:

> DDs are not always involved in caspase activation [the cell death mechanism], and some DDs indirectly suppress apoptosis through effects on NF-kB, a family of transcription factors that have important roles in host defense and cell survival. (Exhibit 1096, page 10, right column, lines 2-5)("The Domains of Apoptosis: A Genomics Perspective," published June 29, 2004).

We think this published statement of Dr. Reed more accurately reflects the complex nature of the cascade resulting in cell death and has more indicia of reliability than his litigation testimony (Exhibit 2064, paragraph 14). Dr. Reed notes "[t]he output of this network of protein interactions determines whether certain effectors of apoptosis become activated in sufficient quantities to commit a cell to death. Most prominent in cell death decisions are (vi) the caspase family cell death proteases mentioned above, but other effectors such as (vii) the CIDE domain-containing apoptotic endonucleases" (*Id.*, page 2, column 1). He further observes:

> In addition to these seven domain families [Apoptosis domains, including DD] that constitute core components of the apoptosis machinery, several families of proteins containing other types of domains have been implicated either in the regulation of the core apoptotic machinery or in the control of closely linked inflammatory response pathways. These protein families minimally include (i) tumor necrosis factor (TNF) family ligands; (ii) TNF receptors (TNFRs): (iii) TIR (toll and IL-1 receptor) domains; (iv) pyrin domains [also called PAAD, for pyrin, AIM (absent –in-melanoma), ASC (apoptosis-associated speck-like protein containing a CARD [caspase-recruitment domain]) and DD-like]; Pyk; or DAPIN (domain in apoptosis and interferon response); (v) TRAFs (TNF receptor-associated factors); (vi) REL (NF-kB) and IkB family proteins; and

> (vii) BAG (Bcl-2-associated athanogene) domains. These domain families will be addressed here only superficially. Other genes and their encoded proteins that play critical or contributory roles in apoptosis regulation or execution will be introduced here only briefly. (*Id.*, page 2, column 2).

Apoptosis is a complex mechanism. It is initiated, enhanced, regulated, inhibited, stopped, and controlled by the complex interaction of myriad proteins, whose form and structure influence their activity as much as their raw sequence does.

In 2002 Dr. Reed looked at 13 domains in an apoptosis domain database, and found that nine of the 13 did not have direct involvement in apoptosis. He concluded that that the mere presence of a death domain does not automatically define a protein's involvement in apoptosis. (Exhibit 1095, p. 622, col. 2). We agree with that statement.

We find these non-litigation oriented publications more persuasive than Dr. Reed's current testimony, and find that, under the specific facts of this case, the identification of DR5 alone is insufficient to describe and enable the subject matter of counts 1 and 2, namely the agonistic or antagonistic antibodies for DR5.

In HGS reply 3 (Paper 64, page 2) HGS states only that "Dr. Reed's publications, cited by Adams, do not state or imply that death domain-containing TNFRs do not induce apoptosis. (MF 352-353, 355)." But that argument misses the point. The point at issue is whether the identification of DR5 along with tests for antibodies describes and enables an embodiment within the scope of the counts.

Dr. Reed and HGS in their motion 3, reply 3, and Declaration of Dr. Reed (Exhibit 2064) conclude that "it would have been reasonable, by March 17, 1997, to believe that antibodies directed against the DR5 protein

would be capable of either inducing or blocking apoptosis." (Exhibit 2064, paragraph 49).

We are not persuaded that Dr. Reed's current position that it would have been reasonable for one of ordinary skill in the art to think that it would work is enough to show possession of an enabled embodiment of the count. First, the sequence of DR5 alone is not a complete characterization of the protein. Second, there is no evidence that isolated monoclonal antibodies would be successfully raised. Third, there is no evidence that the isolated monoclonal antibodies would be agonistic, antagonistic, inert, or variable depending on circumstances.

The evidence, on balance, suggests that the field is complex, unpredictable, and that the similarities might suggest a plan for further research into DR5, but alone is insufficient to support an enabled embodiment of the count. We also conclude that simple identification of screening tests for agonist and antagonist antibodies is insufficient to make the leap that HGS has made - to possession of an enabled embodiment the invention within the count. As noted above, the biochemical pathways resulting in apoptosis are complex. At best, identification of a death receptor-like protein suggests further investigation, and is not sufficient evidence to demonstrate possession of the antagonist or agonist antibodies.

Accordingly, HGS motion 3 is DENIED.

**F. Genentech Motion 2 for Benefit**

Genentech Motion 2 (Paper 43) is a contingent motion to be accorded benefit, with respect to count 1 and count 2, of Provisional Application 60/074,119, filed February 9, 1998. Genentech Motion 2 is also a contingent motion for benefit, with respect to count 1 and count 2, of Provisional Application 60/046,615, filed May 15, 1997, contingent on the

grant of HGS Motion 3 for benefit. As we have denied HGS motion 3, we dismiss this motion as it pertains to Provisional Application 60/074,119 and Provisional Application 60/046,615.

We observe that the Board's Order of October 25, 2007 (Paper 26, page 2) authorized only a contingent motion for benefit to these applications. Genentech states that it now deems the motion as it pertains to the '119 application as not contingent. Genentech states that it "requested" a conference call, but that it "could not be arranged" prior to the filing of the motion. (Paper 43, pages 2-3). In the absence of authorization by the APJ of a noncontingent motion, this motion remains contingent.

Genentech Motion 2 is therefore DISMISSED.

**G. HGS Motion 7 – to Exclude Evidence**

HGS motion 7 is a motion to exclude three pieces of evidence, Exhibit 1103; Exhibit 2161, and Exhibit 2162. As we have not relied upon any of these pieces of evidence in rendering the decision above, the motion is moot. Accordingly, HGS Motion 7 is DISMISSED.

**H. HGS Renewed Motion 2 – Additional Discovery**

HGS Motion 2 (Paper 31) is before the panel on a request for rehearing (Paper 53) of the decision (Paper 51) denying the request for additional discovery.

The request is not really a request for rehearing, it is more along the lines of an unauthorized renewed request for compelled discovery in that it brings forth much evidence which was not present in the original motion.

We, accordingly, DISMISS the paper styled "request for rehearing" as an unauthorized paper.

Even if we were to consider the request for rehearing, we would alternatively deny it on its merits. Additional discovery is provided only if

the requesting party can demonstrate that providing the additional discovery is "in the interests of justice." 37 C.F.R. § 41.150(c). No such showing has been made, and as a consequence the initial decision did not misapprehend or overlook appropriate law or fact.

Each of the three requests relate to a "Material Transfer Agreement" between Human Genome Sciences and the University of Michigan. The argument in support of the relief requested is that the University of Michigan has failed to produce documents under the MTA in a timely manner.

We note that the MTA appears to have been initially executed in 1994, and amended in 1996 and 1997 (Order, Additional Discovery, January 12, 2006)(Paper 51, page 2, finding of fact 11).

HGS initially made its request of the University of Michigan in a letter dated October 12, 2005, after the instant interference was declared. In other words, about 11 years after execution of the agreement, HGS is now requesting the Board to enforce the original agreements.

Paragraph 12 of the agreement reads as follows:

> 12. During the period of Research, Recipient [University of Michigan] shall provide to HGS at least once every three (3) months a summary of the results of Recipient's work under Appendix B utilizing the materials.

As the initial decision states, much of the information HGS desires it appears to have been entitled to under the agreement (Paper 51, page 6, lines 6-7). HGS should already have quarterly reports (at least) from the University of Michigan over the life of the agreement, plus whatever other notifications regarding discoveries were required to be made under the contract. HGS does not clearly state whether it does.

HGS could have pursued its rights when it was administering the research agreement with the University and obtained the reports and

documents to which it was entitled. HGS could have pursued its rights and obtained the underlying documentation when it filed the application which resulted in patent 6,872,568 (May 04, 2000). So far as the evidence before us shows, HGS did neither at those times. Consequently, Michigan's inquiry, allegeded to be a stall, as to "what documents HGS is alleging that it never received but was entitled to under the MTA" is not unreasonable on its face.

We therefore find no reason to disturb the Board's decision finding that HGS did not use the reasonable means available to it.

Second, it appears to us a more appropriate forum for the enforcement of this particular research agreement against Michigan is in state court. That court has a more general jurisdiction to enforce its orders and compel discovery. It also could simultaneously entertain ancillary claims for relief, such as any misappropriation of trade secrets by former employees, which might exist and which would be beyond our jurisdiction.

HGS's request for rehearing of HGS Motion 2 is DISMISSED and alternatively is DENIED.

**I. Order**

Upon consideration of the motions and supporting evidence, and for the reasons given, it is:

**ORDERED** that the request for rehearing of HGS Miscellaneous Motion 2 (Paper 31) to compel testimony and the production of documents, and to grant additional discovery is **DISMISSED** and in the alternative **DENIED.**

FURTHER **ORDERED** that HGS Substantive Motion 3 (Paper 37) to change benefit is **DENIED**.

FURTHER **ORDERED** that HGS Substantive Motion 4 (Paper 38) to substitute new counts 3 and 4 is **DENIED**.

FURTHER **ORDERED** that HGS Motion 7 (Paper 78) to exclude evidence is **DISMISSED**.

FURTHER **ORDERED** that Genentech Substantive Motion 1 (Paper 42) to designate claims as corresponding to the count is **DENIED**.

FURTHER **ORDERED** that Genentech Substantive Motion 2 (Paper 43) for benefit of earlier filed applications is **DISMISSED**.

FURTHER **ORDERED** that Genentech/Adams Responsive Motion 3 (Paper 48) for benefit of earlier filed applications is **DISMISSED**.

/Richard E. Schafer/
RICHARD E. SCHAFER
Administrative Patent Judge

/Michael P. Tierney/
MICHAEL P. TIERNEY
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

/ James T. Moore/
JAMES T. MOORE
Administrative Patent Judge

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# EXHIBIT 6

This order is not binding precedent of the Board.

Paper 109

Filed by: Richard E. Schafer
Administrative Patent Judge
Mail Stop Interference
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Fax: 571-273-0042

Filed: November 30, 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camella W. Adams, Avi J. Ashkenazi,
Anan Chuntharapai, Kyung Jin Kim).

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Patent Interference No. 105,361 (RES)

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**Order - Priority Times - Bd.R. 104(c)**

**A. Conference Call**

A conference call to discuss priority matters is scheduled for **January 4, 2008 at 4:00 p.m.** (PTO time). The call will be placed by the PTO.

**B. Time periods associated with priority**

The TIME PERIODS described below are set out in an Appendix to this ORDER. Action specified for each TIME PERIOD must be completed by the date specified for the TIME PERIOD.

The parties are authorized to stipulate different times (earlier or later, but not later than TIME PERIOD 17) for TIME PERIODS 11 through 16.[1] A notice of the stipulation must be promptly filed. The notice must be in the form of a photocopy of the Appendix attached to this ORDER with old dates crossed out and new dates inserted by hand. The parties may not stipulate an extension of TIME PERIODS 17-19.

**1. TIME PERIOD 11**

The junior party must:

a. File and serve a motion on priority.

b. Serve but not file evidence in support of the junior party priority case.

If the junior party does not file a priority motion, the junior party must arrange a conference call to the administrative patent judge so that appropriate action may be taken.

**2. TIME PERIOD 12**

The senior party must:

a. File and serve a motion on priority and

[1] In stipulating different times, the parties should consider the effect of the stipulation on times (1) to object to evidence (5 business days, Bd.R. 155(b)(1)), (2) to supplement evidence (10 business days, Bd.R. 155(b)(1)), (3) to begin cross-examination (no earlier than 21 days after service, SO ¶ 157.3.1) and (4) to conclude cross examination (at least 10 days before opposition or reply is due, SO ¶ 157.3.2).

b. Serve but not file evidence in support of the senior party priority case.

**3. TIME PERIOD 13**

a. File and serve oppositions to all priority motions and

b. Serve but do not file evidence in support of these oppositions.

**4. TIME PERIOD 14**

a. File and serve replies to all oppositions and

b. Serve but do not file evidence in support of these replies.

**5. TIME PERIOD 15**

a. File and serve any request for oral argument on priority,

b. File and serve motions to exclude evidence (Bd.R. 155(c); SO & 155.2),

c. File and serve observations on cross examination (SO & 157.7) of reply testimony, and

d. File and serve a list of any issues other than priority that should be considered in rendering a final decision in the interference.[2]

**6. TIME PERIOD 16**

a. File and serve oppositions to an opponent's motion to exclude evidence and

b. File and serve any response to observations.

**7. TIME PERIOD 17**

File and serve replies to oppositions to motions to exclude evidence.

[2] There is no need to list an issue previously resolved by a decision entered by a panel of at least three administrative patent judges inasmuch as these decisions merge with the judgment when a final decision is entered.

**C. Deposition transcripts**

Transcripts of cross examinations and depositions taken under 35 U.S.C. § 24 must be served, but not filed until the exhibits are filed.

**D. Serving priority exhibits**

An exhibit, including an affidavit, relied upon in connection with priority must be served but not filed with the motion, opposition, reply or affidavit in which the exhibit is first mentioned.

**F. TIME PERIOD 18: Filing the priority record**

1. File original set of your exhibits and one copy of your exhibits;
2. For your priority motion, file one folder (three folders if an oral argument is set each) containing a set of motion documents consisting of:
   a. The priority motion,
   b. Any corresponding opposition,
   c. Any corresponding reply,
   d. Any corresponding observations, and
   e. Any corresponding response to the observations.
3. File any CD-ROM.

**G. TIME PERIOD 19: Default oral argument date**

If a request for oral argument (Bd.R. 124(a); TIME PERIOD 15) is granted, the default date for such oral argument is TIME PERIOD 19. No oral argument will occur if either no oral argument is requested or granted.

/Richard E. Schafer/
RICHARD E. SCHAFER
Administrative Patent Judge

cc (FAX):

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**Appendix--ORDER - RULE 123(a)**
**(Times for priority motions)**
Interference 105,361 (RES)

TIME PERIOD 11 ..... **February 6, 2008**
Junior party only file priority motion and serve
(but do not file) priority evidence

TIME PERIOD 12 ..... **March 19, 2008**
Senior party only file priority motion and serve
(but do not file) priority evidence

TIME PERIOD 13 ..... **April 30, 2008**
File opposition to priority motions
Serve (but do not file) opposition evidence

TIME PERIOD 14 ..... **June 11, 2008**
File reply
Serve (but do not file) reply evidence

TIME PERIOD 15 ..... **July 23, 2008**
Request oral argument
File list of issues to be considered
File observations
File motion to exclude

TIME PERIOD 16 ..... **August 13, 2008**
File response to observations
File opposition to motion to exclude

TIME PERIOD 17 ..... **August 27, 2008**
File reply to opposition to motion to exclude

TIME PERIOD 18 ..... **September 3, 2008**
File and serve exhibits
File sets of priority motions
File CD-ROMs

TIME PERIOD 19 ..... **October 1, 2008**
Default oral argument date (if ordered)

# EXHIBIT 7

112

Filed on behalf of: Party Ni
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)



Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.
Senior Party
(Application 10/423,448
Inventors: Camella W. Adams, Avi J. Ashkenazi,
Ana Chuntharapai, Kyung Jin Kim).

Patent Interference No. 105,361 (RES)

**HGS'S INTENTION TO NOT FILE A PRIORITY MOTION**

During the teleconference with the Board of January 4, 2008, HGS discussed that it might not file a priority motion in this interference in light of the Board's earlier rulings, but in action under 35 U.S.C. § 146 would seek review of those earlier rulings and with any modification thereof will seek judgment of priority. HGS now confirms that it has chosen that course of action. HGS respectfully submits, however, that the Board should not enter judgment of priority now.

During the January 4 teleconference, HGS requested authorization to file a motion for judgment of the unpatentability under 35 U.S.C. §§ 102(e) and 103 of Genentech's involved claims over HGS's involved patent. As mentioned in the teleconference, HGS sought authorization of such a motion during the motions phase, but such authorization had been earlier denied. *See* Paper 26, p. 3. The Board has not yet ruled on HGS's request for authorization during this phase. HGS respectfully submits that HGS's motion for unpatentability of Genentech's involved claims over HGS's involved patent should be authorized, briefed, and resolved before the Board enters judgment in this interference.

On January 10, 2008, HGS contacted the Board's personnel to arrange for a teleconference to discuss HGS's intent regarding filing a priority motion. That teleconference has not yet been scheduled. From the discussions with the Board's personnel, it appears that the Board might view such a teleconference as unnecessary in light of the January 4 discussion and might prefer the prior filing of a written submission. Hence, HGS submits this paper.

Paper 109 sets forth that if HGS does not file a priority motion, HGS should arrange a teleconference so that appropriate action may be taken. Paper 109, p. 2. Pursuant to Paper 109 and in light of this submission, HGS will contact the Board's personnel to schedule such a teleconference.

Dated: February 4, 2008

Respectfully Submitted,

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**CERTIFICATE OF FILING**

I hereby certify that a copy of the foregoing paper is being filed by Federal Express on this February 4, 2008 in an envelope addressed to:

The Board of Patent Appeals and Interferences
Madison Building East 9th Floor
600 Dulany Street
Alexandria, VA 22314

Michael J. Freno
Reg. No. 57,163

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing paper is being served on the following by Federal Express on this February 4, 2008:

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# EXHIBIT 8

Paper 113
Filed: February 20, 2008

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camella W. Adams, Avi J. Ashkenazi, Anan Chuntharapai).

---

Patent Interference No. 105,361 (RES)

---

*Before*: RICHARD E. SCHAFER, MICHAEL P. TIERNEY and JAMES T. MOORE, *Administrative Patent Judges*.

SCHAFER, *Administrative Patent Judge*.

**Order - Miscellaneous - Bd.R. 104(a)**

Human Genome Sciences (HGS) has filed a paper stating (1) that it would not be filing a priority motion and (2) requesting authorization to file a motion that Genentech's involved claims are unpatentable. (Paper 112) HGS' request is denied.

This interference was declared August 31, 2005. During the interference, the parties sought authorization to file certain motions. Among others, HGS requested authorization to file a motion for unpatentability asserting that all of Genentech's claims were anticipated under 35 U.S.C. § 102(e) over the disclosure of HGS' involved patent. (Paper 23, p. 2, ¶ 12) That motion was not authorized. (Paper 26, p. 2) No request for reconsideration was filed. Subsequently the parties filed their authorized motions and a decision on those motions was entered on November 27, 2007 (Paper 107). The interference then entered the priority phase with the setting of a schedule for filing priority motions. (Paper 109) The time for HGS to file its priority motion was set for February 6, 2008. HGS has indicated that it would not file that motion. (Paper 112) HGS now seeks authorization to attack the patentability of Genentech's claims on the same basis as previously requested in Paper 23. In effect, HGS seeks to revisit the earlier decision declining to authorize the motion.

The fundamental purpose of an interference is to determine priority between two rival claimants of an invention. A separate determination of the patentability of a party's claims, while permitted, is not required. "The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability." 35 U.S.C. § 135(a). HGS' request for authorization to file an unpatentability motion during the "motions" phase of the interference was denied. Paper 26, p. 2. HGS did not request reconsideration of that denial. HGS' reasons

for requesting authorization to file the same motion at this late stage are that the earlier request was denied and the motion should be decided prior to entry of judgment. Allowing HGS to file its motion at this time would likely entail, inter alia, setting times for filing the motion, an opposition and reply, allowing time to cross-examination of any witnesses, and setting time for an oral argument on the motion. In short, permitting the motion at this time would substantially lengthen and increase the cost of this proceeding. HGS' reasons for reopening the motions period at this stage of the proceeding are insufficient. See 37 C.F.R. § 41.1(b) and 41.200(c).

Since HGS was not allowed to file the motion for unpatentability, the estoppel provisions of 37 C.F.R. § 41.127(a)(1) are not applicable with respect to the unpatentability motion based on HGS' involved patent. Thus, HGS has other remedies. For example, HGS may file a protest under 37 CFR § 1.291.

HGS' request is **denied.**

/Richard E. Schafer/
RICHARD E. SCHAFER
Administrative Patent Judge

/Michael P. Tierney/
MICHAEL P. TIERNEY
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

/James T. Moore/
JAMES T. MOORE
Administrative Patent Judge

cc (FAX):

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2

# EXHIBIT 9

Paper 114
Filed: February 20, 2008

Mail Stop Interference
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UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

---

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.,
Senior Party
(Application 10/423,448;
Inventors: Camella W. Adams, Avi J. Ashkenazi, Anan Chuntharapai).

---

Patent Interference No. 105,361 (RES)

---

*Before*: RICHARD E. SCHAFER, MICHAEL P. TIERNEY and JAMES T. MOORE, *Administrative Patent Judges*.

SCHAFER, *Administrative Patent Judge*.

**Judgment - Request for Adverse - Bd.R. 127(b)**

Human Genome Sciences' (HGS) brief on priority was due on February 6, 2008. Paper 109, pp. 2 and 6. HGS filed a paper stating it would not file priority motion. Paper 112. The failure of a junior party to file a priority motion is construed as a concession of priority. Accordingly, it is appropriate to enter judgment.[1] 37 CFR § 41.127(b).

It is

**ORDERED** that judgment on priority as to the subject matter of Counts 1 and 2, Paper 1 p. 3) is awarded against Human Genome Sciences, Inc.;

**FURTHER ORDERED** that Human Genome Sciences, Inc. is not entitled to a patent containing claims 1-6, 8-19, 21-32, 34-45 and 47-52 (corresponding to Count 1) or claims 7, 20, 33, 46 (corresponding to Count 2) of Patent 6,872,568;

**FURTHER ORDERED** that claims 1-52 of Patent 6,872,568 be CANCELED, 35 U.S.C. § 135(a);

**FURTHER ORDERED** that a copy of this judgment be made of record in the file of Patent 6,872,568, and Application 10/423,448; and

**FURTHER ORDERED** that if there is any settlement agreement which has not been filed, attention is directed to 35 U.S.C. §135(c) and 37 CFR § 41.205.

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[1] Genentech's request for reconsideration of the decisions on interlocutory motions (Paper 110) is dismissed as moot in view of the entry of judgment.

| | |
|---|---|
| /Richard E. Schafer/ | ) |
| RICHARD E. SCHAFER | ) |
| Administrative Patent Judge | ) |
| | ) |
| /Michael P. Tierney/ | ) BOARD OF PATENT |
| MICHAEL P. TIERNEY | ) APPEALS AND |
| Administrative Patent Judge | ) INTERFERENCES |
| | ) |
| /James T. Moore/ | ) |
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# EXHIBIT 10

THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY

# EXHIBIT 11

Paper 39
12-8-5
55

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Party Adams, Inc.
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim)

Patent Interference No. 105,361 (RES)

**PARTY NI SUBSTANTIVE MOTION 5**
(For Sanctions Against Party Adams)

## I. *STATEMENT OF PRECISE RELIEF REQUESTED*

Junior Party Ni ("Party Ni") hereby moves under 37 C.F.R. § 41.128 for sanctions by the Board against Senior Party Adams ("Party Adams") in view of Genentech's blatant, unauthorized *ex parte* protests against the issuance of a patent to Party Ni. Party Ni requests that the Board enter judgment in the interference in favor of Party Ni under 37 C.F.R. § 41.128(b)(8). Alternatively, Party Ni requests that the Board consider the following remedies: (a) Party Ni requests that the Board exercise its authority under 37 C.F.R. § 41.128(b)(3) and preclude Party Adams from presenting the issue of whether it is entitled to the benefit of priority of its earlier U.S. Application Nos. 60/074,119 (filed February 9, 1998) and 60/049,615 (filed May 15, 1997); (b) Party Ni requests that the Board change the benefit accorded to Party Adams for the contested subject matter under 37 C.F.R. § 41.128(b)(1) by denying Party Adams the benefit of U.S. Application Nos. 10/288,917; 10/052,798; and 09/079,029, to which priority was accorded in the Declaration of Interference in the present matter (Paper No. 1); and (c) Party Ni requests that the Board exercise its authority under 37 C.F.R. § 41.128(b)(3) to preclude Party Adams from contesting the issue of the benefit to be accorded to Party Ni, because Party Adams has already improperly taken multiple opportunities to present its arguments on this issue in its unauthorized protests of Party Ni's applications. Each of these requested sanctions is fully within the jurisdiction of the Board and is appropriate in view of Party Adams' behavior.

## II. *EVIDENCE IN SUPPORT OF THE MOTION*

A list of Exhibits relied upon by Party Ni may be found at Appendix A, attached hereto.

## *III. STATEMENT OF MATERIAL FACTS*

The Statement of Material Facts may be found at Appendix B, attached hereto.

Charts depicting the family trees of Party Adams' TRAIL-R2 applications and Party Ni's TRAIL-R2 applications may be found at Appendices C and D, respectively, attached hereto.

## *IV. ARGUMENT*

### *A. Party Adams Engaged in Inappropriate Conduct During the Prosecution of its '746 and '448 Applications*

Prior to the declaration of the present interference, Party Adams repeatedly and improperly protested the issuance of the involved patent to Party Ni, in violation of 37 C.F.R. § 1.291 ("Rule 291"). To safeguard the *ex parte* system for securing a patent, the PTO prohibits third party protests, except under the strict guidelines of Rule 291. As discussed below, Party Adams violated Rule 291 by, *inter alia*, repeatedly arguing to the USPTO that any patent that could or may issue from Party Ni's application would not be valid without making any attempt to comply with the procedural requirements of Rule 291. By circumventing the proper procedures, Party Adams' protests effectively denied Party Ni its right to *ex parte* prosecution. Party Adams' inappropriate conduct constituted repeated third party protests of Party Ni's applications, and should be sanctioned.

U.S. Patent Application No. 09/020,746 ("the '746 application"), assigned to Genentech, and U.S. Patent Application No. 09/565,009 ("the '009 application"), assigned to Human Genome Sciences, were both pending before Examiner Claire Kaufman at the USPTO from May of 2000 to March of 2005. (Facts 5, 6) The '009 application then issued as U.S. Patent No. 6,872,568, which is the involved patent in the present interference. (Fact 2) The '009 application

claims priority to several applications, including U.S. Provisional Patent Application No. 60/040,846 ("the '846 application"). (Fact 1) On at least three occasions during the co-pendency of the '009 and '746 applications, Party Adams submitted written statements to Examiner Kaufman protesting the issuance of a patent based on Party Ni's '009 application. (Facts 9-11, 13, 15, 17, 23, 25) For example, in a Miscellaneous Communication submitted to Examiner Kaufman on February 14, 2005 in the '746 application, Party Adams noted that Party Ni's '009 application had been allowed, but asserted that "any patent that could or may issue from the [Party Ni] '009 application *would not be valid.*" (emphasis added). (Fact 25)

Party Adams submitted its protests under the guise of being communications related to the prosecution of its own '746 application. However, Party Adams submitted these protests in the absence of *any* outstanding rejection in the '746 application in a clear attempt to circumvent the interference procedures. (Facts 8, 16, 24) Party Adams also inappropriately submitted declarations under 37 C.F.R. § 1.131 ("Rule 131") to allegedly "swear behind" Party Ni's copending applications, even though both Party Ni's and Party Adams' applications claimed the same inventions. These declarations contained all-out attacks on the enablement, written description and utility disclosures of Party Ni's priority documents, and were a clear abuse of Rule 131. Moreover, because Party Adams failed to comply with Rule 291 and submitted these improper declarations in its own application, Party Ni had no effective opportunity to reply. Thus, through its repeated improper submissions, Party Adams sought to circumvent the jurisdiction of the Board and have the Examiner determine priority.

The submission of such a protest by a third party is not permitted under the rules, based on the clear intent of Congress and the Office as reflected in 35 U.S.C. § 122(c) and Rule 291. *See* 1269 Off. Gaz. Pat. Office 179. Party Adams did not even feign to comply with Rule 291 in any of its PTO communications. Instead, Party Adams repeatedly attempted to improperly influence Examiner Kaufman to prevent the issuance of a patent to Party Ni. Because these third party protests circumvented the requirements of Rule 291 and inappropriately intervened in the *ex parte* prosecution of Party Ni's applications, Party Adams should be sanctioned.

**1) Unauthorized third party protests of a pending application are strictly prohibited during *ex parte* prosecution**

Protests by the public against pending patent applications are prohibited, except in very limited circumstances as provided for in 37 C.F.R. § 1.291. Specifically, subsection (a) of the version of Rule 291 in effect at the time of filing of Party Ni's '009 application stated that protests by the public against pending applications will be referred to the examiner and entered into the application if the following requirements are met: (1) the protest is submitted in the protested application, (2) prior to the mailing of a notice of allowance; and (3) the protest is either served on the applicant in accordance with § 1.248, or filed with the Office in the event that service is not possible. Subsection (b) of Rule 291 detailed what documents are required in a protest, including a listing and copies of the patents, publications, or other information relied upon and a concise explanation of the relevance of each listed item. 37 C.F.R. § 1.291(b)(1997). Subsection (c) of Rule 291 limited the involvement of the member of the public filing a protest,

and prohibited further submissions in the absence of new facts or issues. 37 C.F.R. § 1.291 (1997).

Congress has expressed its clear intent that pre-issuance protests must be carefully regulated after pending applications are made accessible to the public:

> The Director shall establish appropriate procedures to *ensure* that no protest or other form of pre-issuance opposition to the grant of a patent on an application may be initiated after publication of the application without the express written consent of the applicant.

35 U.S.C. § 122(c) (emphasis added). Based on this mandate, the Office amended Rule 291 to prohibit protests after an application was published. *See* Third Party Attempts to Protest or Otherwise Oppose the Grant of a Published Application, 1269 Off. Gaz. Pat. Office 179 (April 22, 2003)(Exhibit 2044). In doing so, the Office specifically noted that Rule 291 (and public use proceedings pursuant to Rule 292) constitute "the only forms of third party protest or pre-issuance opposition to a pending application permitted by the rules of practice." *Id.*

The Federal Circuit has also made it clear that the *ex parte* prosecution of patent applications is not to be disrupted by third parties. *See Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930; 18 USPQ2d 1677 (Fed. Cir. 1991). In *Animal Legal Defense Fund*, a third party sued to enjoin the USPTO from issuing patents directed to animals. The Court held that third parties do not have a right to intervene in the prosecution of another's patent application and prevent issuance of an allegedly invalid patent. *See id.* at 930 ("we find nothing in the law which gives rise to a right in nonapplicants to object to the way in which patent applications of others are prosecuted").

In fact, the Board of Patent Appeals and Interferences has found motions relating to patentability of applications in cases in which an interference has been terminated to be improper protests. *See Han v. Livak*, 63 U.S.P.Q.2d 1364 (BPAI 2002) (Board declined to decide the merits of Livak's motion regarding patentability of Han's involved claims because the interference had been terminated and the motion amounted to an inappropriate third party protest), *see also Petrie v. Welsh*, 21 U.S.P.Q.2d 2012 (BPAI 1991)(Board interpreted Welsh's request for a post-termination decision on the issue of validity of Petrie's claims as an improper third-party attempt to oppose the grant of Petrie's patent, and held that an individual does not have a right to intervene in the prosecution of a particular application to prevent issuance of a patent sought by another).

It is immaterial that in this case Party Adams protested Party Ni's application *before* getting involved in the present interference, while in the cited cases, Livak and Welsh attempted to protest pending applications *after* having been involved in an interference. The Board in *Han* and *Petrie* made it clear that *ex parte* interventions are forbidden, and the reasoning in both instances applies equally well in this situation. A third party should not be able to attack a pending application either *before or after* an interference proceeding. In such situations, the Board has instructed would-be third party protestors to submit such arguments under Rule 291. *See Han v. Livak*, 63 U.S.P.Q.2d 1364 (BPAI 2002). These holdings emphasize the importance of the procedures set forth in the rule, as well as the PTO's reliance on those procedures. Thus, if a member of the public wishes to protest an application, Rule 291 provides mechanisms and guidance for doing so.

**2) Party Adams' protests of Party Ni's application violated 37 C.F.R. § 1.291**

Party Adams had the option to properly submit a protest to the PTO regarding Party Ni's pending applications under Rule 291, but chose instead to disregard the rules and submit its protests *via* its '746 application to Examiner Claire Kaufman, who was assigned to examine both Party Ni's '009 application and Party Adams' '746 application. Party Adams' protests of Party Ni's '009 application did not comply with Rule 291 for many reasons. First, Party Adams made no effort to provide the protests or notice thereof to Party Ni. Party Ni was not served with notice of the submissions, nor was the protest filed in Party Ni's applications, and there is no indication in Party Adams' file history that copies of the submissions were filed in duplicate with the Office. (Facts 14, 18, 26) Second, Party Adams' protests further violated Rule 291 because Party Adams submitted at least three protests of the same applications, presenting the same assertions of invalidity on different dates, which was prohibited by the rule at that time. (Facts 9-11, 13, 15, 17, 23, 25) Third, the February 14, 2005 protest also violated additional procedural requirements that went into effect on November 22, 2004 as part of amended Rule 291. In addition to the above-listed violations, the February 14, 2005 protest: (1) was filed after the mailing of a Notice of Allowance in Party Ni's '009 application, without consent from the applicant, Party Ni, and (2) did not contain an explanation of what new issues necessitated multiple protests of the same application. (Facts 20, 22, 25, 34) Thus, all three protests by Party Adams of Party Ni's '009 application were prohibited by Rule 291, and therefore should not have been considered by the examiner.

**a) Party Adams' January 22, 2003 protest violated Rule 291**

On January 22, 2003, Party Adams submitted to Examiner Kaufman in its '746 application a 16-page Supplemental Amendment and Reply accompanied by three Declarations under 37 C.F.R. § 1.131, and a Supplemental IDS and Form PTO-1449 disclosing several patents and applications. (Facts 9-13) Party Adams also submitted copies of the listed patents and applications, including Party Ni's priority '846 application and '009 application. (Fact 12) Party Adams noted in the Supplemental IDS that it was able to obtain copies of the '009 application through related published applications. (Facts 7,13, Exhibit 2041) Party Adams' failed to comply with Rule 291 in its January 22, 2003 submission because it failed to serve Party Ni with notice that its application was being attacked, it failed to file the protest in Party Ni's application, and there is no indication that duplicate submissions were presented to the Office. (Facts 9, 14)

Party Adams' January 22, 2003 Amendment and Supplemental Response contained lengthy and unprovoked arguments directed to the co-pending [Party Ni] '009 application and the [Party Ni] priority '846 application, which are excerpted here:

> *In an effort to resolve any potential issues that the Examiner could raise* in respect to these three families of applications, Applicant respectfully submits the following *arguments.* Applicant also herewith provides three declarations under 37 C.F.R. 1.131 executed by the inventor of the present application in respect of each of the three families discussed below. *Applicant respectfully submits that no patent could issue on the basis of any of these families of applications which would be entitled to an effective filing date prior to that of the present application for the presented claims*....[detailed argument omitted]
>
> *In view of these considerations, Applicant submits that the '846 application does not disclose a specific, substantial and credible utility for the DR5 sequence.*

(emphasis added). (Fact 10)

Dr. Avi J. Ashkenazi, a named co-inventor of Party Adams' patent application involved in the present interference, filed a Declaration under 37 C.F.R. § 1.131 (Rule 131) on January 22, 2003. (Facts 9, 11) Rule 131 allows for the filing of a declaration as a means of "swearing behind" a reference or activity in order to overcome a *rejection* during prosecution. 37 C.F.R. § 1.131. The PTO drafted Rule 131 in such a way as to prevent applicants from using it to avoid interferences by inappropriately arguing for priority during *ex parte* prosecution. *See* 53 FR 23728 (1988); 60 FR 21043(1995). In fact, the rule itself explicitly states that provoking an interference is the appropriate action to take when an applicant believes the same invention is claimed in a patent application and patent (or second pending application). 37 C.F.R. § 1.131. When Party Adams submitted Dr. Ashkenazi's Declaration, it was not facing a rejection over any of Party Ni's applications. (Fact 8) While "swearing behind" prior art that has not been cited is sometimes practical and efficient, that is not what happened here. Rule 131 prohibits the use of a Rule 131 Declaration to argue for priority over another patent (or pending application) claiming the same patentable invention. *See* 37 C.F.R. § 1.131. Yet, Dr. Ashkenazi's unwarranted Rule 131 Declaration asserted the unpatentability of Party Ni's '846 priority application. (Fact 11) Additionally, the Rule 131 Declaration contained assertions for priority of Party Adams' '746 application over any progeny of Party Ni's '846 priority application. (Fact 11) For example, Dr. Ashkenazi's Declaration stated:

> [Party Ni's] '846 application does not provide information as to how the claimed sequences were identified or particularly, what materials or methods were used to identify the claimed sequences....[detailed argument omitted]
>
> *For at least these reasons, I believe the '846 application does not and cannot provide an adequate basis to determine the specific biological functions of the*

> *putative DR5 receptor disclosed in the '846 application.... These factors, considered in light of the standards for evaluation of utility articulated in the PTO Utility Examination Guidelines (2001), render the '846 application incapable of establishing a specific, substantial and credible utility for claims directed to the DR5 sequence.*

(emphasis added). (Fact 11) Party Adams used the subterfuge of a Rule 131 Declaration to improperly allege that Party Ni's priority application lacked enablement and utility.

**b) Party Adams' February 28, 2003 protest violated Rule 291**

Although the PTO had not yet responded to its January 2003 Supplemental Reply (Facts 14-16), on February 28, 2003, Party Adams submitted to Examiner Kaufman a Second Supplemental Response in its '746 application, which contained the following remarks relating to Party Ni's '009 and priority '846 applications:

> Applicant notes that in the first supplemental response filed January 22, 2003, *references were made to certain provisional and non-provisional applications filed by third parties*, the existence, contents and status of which are public record. These applications include, *inter alia*, the following: ...*Provisional Application No. 60/040,846,* filed March 17, 1997, now abandoned....
>
> Applicant noted in the first supplemental response that the above-referenced applications are the subject of priority claims under 35 U.S.C. 119(e) and 120 of certain other applications, one or more of which may be pending before the Office. *As indicated in the first supplemental response, none of the above-referenced applications describes or could adequately support the invention defined in the claims of the present application under 35 U.S.C. 101 and 112, first paragraph.*

(emphasis added) (Facts 15, 17) Party Adams again violated Rule 291 by submission of these assertions because it failed to serve a copy of the protest on Party Ni, or provide duplicate copies to the Office. (Fact 18) Party Adams further violated Rule 291 because this second protest did

not present any new issues that had not been previously presented in the January 22, 2003 protest, and it was therefore a prohibited second protest of the same application. (Fact 10, 11, 17)

**c) Party Adams' February 14, 2005 protest violated Rule 291**

In April of 2003, the PTO suspended prosecution of the Party Adams '746 application for a potential interference. (Fact 19) Prosecution was still suspended in the '746 application when, on January 21, 2005, the PTO entered a Notice of Allowance in the Party Ni '009 application. (Facts 20, 21) After becoming aware of the Notice of Allowance, Party Adams filed its most improper protest in a final attempt to prevent the issuance of a patent based on Party Ni's '009 application. (Facts 23, 25) Specifically, Party Adams submitted a Miscellaneous Communication to Examiner Kaufman in its '746 application, in which it stated:

> Based on public information available on the PTO PAIR database, Applicant understands that prosecution of the instant application has been suspended in light of [Party Ni's] co-pending USSN 09/565,009 (the '009 application).
>
> *Applicant has recently become aware, based on public information provided via the PTO PAIR database, that the Office mailed a Notice of Allowance for the '009 application on 1/21/05.* Because information pertaining to the allowance and/or issuance of the '009 application may be of relevance to the prosecution of the instant application, Applicant believes it appropriate to bring this information to the Examiner's attention.
>
> Applicant also observes that in at least two previous communications to the Office during the prosecution of the instant application (e.g., the Supplemental Responses filed on 1/22/03 and 2/28/03), *Applicant provided information and evidence that the '009 application (or a patent that issues therefrom) cannot be prior art to the instant application and cannot support claims to subject matter presently claimed in this application.* For example, Applicant submitted a §1.131 declaration on 2/28/03 that antedates the earliest filing date claimed by the '009 application, i.e., March 17, 1997. *Because of this, Applicant believes that any patent that could or may issue from the '009 application would not be valid.*

(emphasis added). (Facts 23, 25)

Party Adams was faced not with a new rejection - but rather the potential issuance of a competitor's patent. Party Adams filed its protest in its own application in an effort to persuade the Examiner to reconsider her decision in allowing the '009 application. By improperly filing a protest with full knowledge that Party Ni's '009 application was allowed, but without Party Ni's written consent, Party Adams effectively opposed the issuance of Party Ni's application - the very conduct the rules were promulgated to prevent. (Facts 20, 22, 23, 34)

Additionally, Party Adams violated Rule 291 by the filing of its February 2005 protest of Party Ni's application because it failed to serve a copy on Party Ni, and there is no indication that the protest was filed with the Office in duplicate, thus giving Party Ni no opportunity to reply. (Facts 23, 26) Party Adams' protest further violated Rule 291 because it was the third prot

# EXHIBIT 12

Paper 99
JS
9-15-6

Filed on behalf of: Party Ni
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
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Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.
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(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).



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Patent Interference No. 105,361 (RES)

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**JOINT SUBMISSION OF REVISED TRANSCRIPT**
**(Of July 27, 2006 Oral Argument)**

Pursuant to the Administrative Patent Judges' request, and as discussed in Adams Submission of Non-Revised Transcript (of July 27, 2006 Oral Argument), filed August 25, 2006, the parties hereby jointly submit a revised version of the transcript.

The undersigned is authorized to file this paper on behalf of both parties.

Respectfully submitted,

Jorge A. Goldstein
Attorney for Party Ni
Registration No. 29,021

Date: September 14, 2006
Sterne, Kessler, Goldstein & Fox P.L.L.C.
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583360_1.DOC

## CERTIFICATE OF SERVICE

I, Jorge A. Goldstein, hereby certify that a copy of the foregoing JOINT SUBMISSION OF REVISED TRANSCRIPT (Of July 27, 2006 Oral Argument), has been served on the attorney of record for each of Party Adams and Party Rauch via Federal Express on this 14th day of September 2006, addressed as follows:

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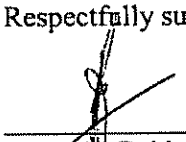
Respectfully submitted,



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Date: September 14, 2006
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**Court Hearing 7/27/06**



UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

(Administrative Patent Judge Richard E. Schafer)

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Human Genome Sciences, Inc.

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Inventors: Camellia W. Adams, Avi J. Ashkenazi,

Anan Chuntharapai, Kyung Jin Kim).

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Patent Interference No. 105,361 (RES)

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Ni EXHIBIT 2168
Ni v. Adams
Interference No. 105,361

**Court Hearing 7/27/06**



Thursday, July 27, 2006

Alexandria, Virginia

The HEARING in the above-entitled matter came on at 2:00 p.m. pursuant to Notice, at before:

Judge Carolyn Spiegel

Judge Richard ~~Shafer~~ Schafer

Judge Adrian Hanlon

Job No. 175645

Pages 1 - 70

Reported by: Sandy Medford Nelson

Thursday, July 27, 2006

3:00 p.m.

Patent Interference Hearing Human Genome Sciences, Inc. and Genentech, Inc. was held at:

Board of Patent Appeals
Madison Building E
600 Dulaney Street
Alexandria, Virginia 22313
(703) 979-0420

Pursuant to agreement, before Sandy Medford Nelson, Notary Public of the State of Virginia.

A P P E A R A N C E S

JUDGE CAROLYN SPIEGEL

JUDGE RICHARD ~~CHAPER~~ SCHAFER

JUDGE ADRIAN HANLON

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Diane Marshang

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Michele ~~Michelle~~ ~~Raile~~ Wales

Joe ~~Schuler~~ Schuller

Sharla ~~Charla~~ Young

Derek ~~Derrick~~ Scott

**Court Hearing 7/27/06**



P R O C E E D I N G S

JUDGE SPIEGEL: We are here today to discuss the pending and currently undecided motions in interference number 105361 between Party Ni, who is assigned to Human Genome Sciences, Incorporated, and Senior Party Adams who's assigned to Genentech, Incorporated. The sitting panel is Judge Adrian Hanlon, myself, Judge Carolyn Spiegel, and Judge Richard Schafer.

What we'd like to do is begin by the counsel introducing themselves, and then we will have Junior Party begin their case presentation. Each side will have 30 minutes. And, if you want to reserve any time for rebuttal, just tell me when you come up.

And, with that, why don't we get started? Senior Party first --

MR. ~~KUCHAN~~ ASHE: Thank you.

JUDGE SPIEGEL: -- for the introduction just because you got up first.

MR. ASHE: My name is Oliver Ashe, and I represent Senior Party Adams. With me today is

backup lead counsel Jeffrey Kushan and Diane Marshang --

JUDGE SPIEGEL: I'm sorry. I can't hear you.

MR. ASHE: Diane Marshang from Genentech and Ed Kenehan from Greenblum & Bernstein, ~~Horr~~ Hanh Nguyen and Wendy Lee. Thank you.

JUDGE SPIEGEL: You're welcome.

MR. GOLDSTEIN: My name is Jorge Goldstein, and I'm together with my co-counsel Eldora Ellison. We represent HGS, and today we have ~~Michelle Raile~~ Michele Wales, Joe ~~Schuler~~ Scholler, ~~Charla~~ Sharla Young and ~~Derrick~~ Derek Scott of Human Genome Sciences.

JUDGE SPIEGEL: Thank you.

MR. GOLDSTEIN: You're welcome.

JUDGE SPIEGEL: Mr. Goldstein, if you could indulge us by starting with your motion number four to substitute count and motion three for benefit, we'd appreciate it.

MR. GOLDSTEIN: Sure, Your Honor.

JUDGE SPIEGEL: Thank you.

MR. GOLDSTEIN: We have requested that

the count, which is presently limited to monoclonal antibodies --

JUDGE SPIEGEL: Can I interrupt you here for --

MR. GOLDSTEIN: Yes.

JUDGE SPIEGEL: -- just a second here? I see you have demonstratives. Do you have copies for the board? Because I, for one, can't see that. I'm sorry. You know, I'm not tall enough.

MR. GOLDSTEIN: That's all right. I have an original.

JUDGE SPIEGEL: Thank you.

MR. GOLDSTEIN: You're welcome.

JUDGE SPIEGEL: And, Mr. Ashe, you've been served copies of this?

MR. ASHE: I believe so, yes. I received it Friday.

MR. GOLDSTEIN: We have served it a few days ago, so I believe that you have our copies.

MR. ASHE: Yes. Thank you.

JUDGE SPIEGEL: Thank you.

MR. GOLDSTEIN: The demo Exhibits 1 and 2

are reproductions of what you have in demo Exhibit 1 and 2, and these are family trees for HGS and Genentech. I would like to reserve five minutes for rebuttal.

JUDGE SPIEGEL: Certainly.

MR. GOLDSTEIN: You requested that I address the motion to substitute the count first.

JUDGE SPIEGEL: If you please.

MR. GOLDSTEIN: Yes. The counts -- there are two counts, one to antagonist monoclonal antibodies and one to agonist monoclonal antibodies, against the Trail R2 receptor, which is an apoptosis-inducing receptor. We have moved to broaden both counts, at least one of the two alternatives, so that the limitation monoclonal antibodies gets dropped in favor of antibodies because our earliest proofs under the ~~Louie v Kato~~ Louis v Okada test do not encompass monoclonal antibodies. They talk about antibodies broadly.

And so, we believe that the justification for broadening the count is based on reasonable grounds. We're not just requesting that the count

be broadened for any old reason and --

JUDGE SPIEGEL: So, if I understand you, the count is directed to the monoclonal antibody to -- and could we use the term DR5, if no ~~none~~ one objects?

MR. GOLDSTEIN: We don't object.

JUDGE SPIEGEL: DR5, which monoclonal antibody is either an agonist or an antagonist thereof, depending on which count?

MR. GOLDSTEIN: Yes.

JUDGE SPIEGEL: So, you're requesting that the count be broadened to just a generic antibody?

MR. GOLDSTEIN: Correct, Your Honor.

JUDGE SPIEGEL: Because your proofs to an antibody which specifically binds to DR5 --

MR. GOLDSTEIN: DR5, that's right. Our best proofs do not recite monoclonal in them, Your Honor. And so --

JUDGE SPIEGEL: But they do recite binding to DR5?

MR. GOLDSTEIN: Well, a combination of

the proofs do, and they will be supplemented at priority phase, but the best proofs that we have -- documentary proofs in hand -- do not recite monoclonal, but they -- but a combination proofs, documentary proofs, recite together antibodies to DR5, yes, Your Honor.

JUDGE SPIEGEL: But you don't have proofs directed solely to an antibody to DR5? You have a series of proofs that somehow gets me there?

MR. GOLDSTEIN: Well, we can make a case -- make a case on priority that shows that we conceived of generating antibodies, not monoclonal -- antibodies to death receptors, and then we have a proof that shows --

JUDGE SPIEGEL: To death receptors generically?

MR. GOLDSTEIN: To any death receptor that is going to be discovered in the future, the earliest proof that we have, at least in hand right now, says that when such a death receptor is discovered and isolated that it would be routine to generate antibodies against it so that one can

make agonist and antagonist antibodies.

A little later in time, there is a proof that shows that such a death receptor, DR5, was actually discovered and isolated and sequenced and identified for function. And those two together show that we have at least documentary proofs that indicate that in the minds of the inventors as corroborated by these proofs in -- had conceived of generating antibodies to DR5.

JUDGE SCHAFER: Mr. Goldstein, let me ask you a question. When you talk about DR5, the counts talks -- and, again, even your proposed change count talks about a specific sequence.

MR. GOLDSTEIN: Yes.

JUDGE SCHAFER: -- DR5 would meet that sequence?

MR. GOLDSTEIN: Yes.

JUDGE SCHAFER: Okay.

MR. GOLDSTEIN: So, our motion under Louis v Okada ~~Louis v Kater~~ motion four I believe, requests that the count be broadened so that these earliest documentary proofs, which are our best proofs,

meet the broader count.

JUDGE SPIEGEL: So, if I'm hearing you correctly, you have a documentary proof to generating an antibody to any old death receptor past, present, future? And then you have a documentary proof that you have discovered a specific death receptor, DR5?

MR. GOLDSTEIN: Um-hum.

JUDGE SPIEGEL: And, from that, we are supposed to deduce that you have priority proofs of an antibody to DR5 --

MR. GOLDSTEIN: Not from that alone, Your Honor. Not from that alone. Obviously, a priority case will entail testimony from the inventors and corroborating witnesses. This is just corroborating documentary proof. It is not the primary proof.

JUDGE SPIEGEL: No. I'm just inquiring into what your proffered proof actually is.

MR. GOLDSTEIN: Yes. My proffered proof is corroborating proof -- it corroborates the basic, primary proof that we will put forth in our

priority case.

JUDGE SCHAFER: So, your proffer is we can prove to you -- given the opportunity, we can prove to you the conception of an antibody?

MR. GOLDSTEIN: To DR5.

JUDGE SCHAFER: To DR5.

MR. GOLDSTEIN: And we will corroborate that proof --

JUDGE SCHAFER: And, right now, you can't because you would have to -- you would have to prove a monoclonal antibody to be able --

MR. GOLDSTEIN: Well, I can't corroborate it with documentary proof, which is what I want to be able to do. I certainly can have primary evidence by the inventor and corroborating witnesses that they conceived of an antibody that was either an agonist or an antagonist to DR5. But what I want to be able to do is produce corroborating documentary proof because the testimony alone isn't going to be enough.

JUDGE SPIEGEL: To draw to an antibody?

MR. GOLDSTEIN: Exactly.

JUDGE SPIEGEL: Because -- what you're saying is your ~~collaboration~~ corroboration goes to antibodies where generally --

MR. GOLDSTEIN: Exactly, Your Honor. That's right. You then requested that I address the motion for benefit.

JUDGE SPIEGEL: Yes.

MR. GOLDSTEIN: Is that correct?

JUDGE SPIEGEL: Yes, sir.

MR. GOLDSTEIN: Yeah. Well, I have shown in these two -- demo one and demo two -- the HGS family tree on the left in demo one, and the Genentech family tree on the right. Green are the assigned priority dates, and these two green boxes are the involved patent and application of the parties respectively. Yellow are the requested benefit, priority benefit. And in a red/purple I have also indicated the existence of a parallel prosecution that occurred --

JUDGE SPIEGEL: Let's just stop right there. Your motion to benefit goes to benefit for ~~you're~~ your involved --

MR. GOLDSTEIN: Yes.

JUDGE SPIEGEL: -- case.

MR. GOLDSTEIN: Excuse me.

JUDGE SPIEGEL: So, why don't we just stick with the first demonstrative?

MR. GOLDSTEIN: Yes, Your Honor. So, we've asked for benefit all the way back to March 17, 1997. The '846 application, that is the earliest ~~file~~ filed application of either party. This application enables, describes and provides a fully credible utility for the two antibodies -- two embodiments under -- one -- one embodiment under each count for an agonist antibody and for an antagonist antibody.

And, at this point, they are monoclonals and we do enable, describe and provide full utility on how to use ~~to~~ monoclonal agonist antibodies to DR5 and monoclonal antagonistic antibodies for DR5 for these two counts.

The discovery of this molecule by Dr. Ni resulted in a determination that the structure of the molecule, the motifs present in the molecule

and their linear sequence -- the order in which these motifs appear, namely a leader sequence, an extracellular domain with two cysteine-rich domains, a ~~transmembering~~ transmembrane domain, and intracellular domain with a death domain in it, and a homology of portions of these domains compared to prior art death receptors like Fas and DR3 and TNFR1 accurately identified this new molecule as another death receptor.

And this is not any old TNFR as our opponents would like you to believe and argue. This is not any old TNFR. This is a TNFR with ~~the~~ a death domain. And it isn't any old protein with a death domain such as intracellular proteins that are involved in signalling. This is a protein with a death domain. It's also a TNFR.

So, the combination of both subsets, the TNFR structure, the homology to prior art and the presence of a death domain in the TNFR accurately identified the molecule as a death receptor. And, in fact, the description is of the sequence and the structure, and there is lots of disclosure on

how one would use that to make monoclonal antibodies that are agonistic and how to verify that these antibodies are agonistic and how to make monoclonal antibodies to them that are antagonistic.

This disclosure is fully in compliance with paragraph one for enablement purposes and certainly Noelle v Lederman which controls written description for antibodies. In fact, Noelle v Lederman is a case that dealt with an antibody to a receptor, a CD40 receptor. And, if you look at the count in Lederman, there was a function in it, and the function had to do with the fact that this antibody in the Lederman case inhibited the bonding of CD40 receptor to CD40. So, it was an antagonistic antibody.

And I bring the board's attention to the case of Capon v Eshhar, which we have briefed. And in Capon v Eshhar at -- and I cite 418 ~~fifth~~ F3d ~~third~~ 1360. In Capon v Eshhar, ~~CFC~~ the CAFC acknowledged that in doing written description for generic claims and ~~by technology~~ biotechnology it is quite all right

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under 112 first paragraph to include experimental verification, even if the concept that is -- that is claimed and claimed to be novel has some variability.

So, the fact that -- as our opponents have pointed out, there are two counts that -- different (in) function that are in some way that have what it -- what they have in common is the structure of this antigen is not fatal to this -- to a ~~termination~~ determination that we have X fully described with a test -- with a step of verification to see whether out of a class of monoclonals that have been made which ones are agonists and which ones are antagonists to comply with 112 first.

So, our position is that these two counts can be fully described under 112 paragraph -- 112 first written description requirements under Noelle, which controls antibody written description 112 first, and Capon. Now --

JUDGE SPIEGEL: Excuse me. Now, if I understand you correctly, then your position is that the disclosure in the applications that

you're requesting benefit of is sufficient to make it obvious to obtain the subject matter of both counts --

MR. GOLDSTEIN: No -- I'm sorry.

JUDGE SPIEGEL: -- that there is not an actual anticipatory description in any of those applications of the subject matter of either count; is that correct?

MR. GOLDSTEIN: No, Your Honor. And I beg to differ respectfully. There is, in fact, an anticipatory description. There is a prophetic constructive reduction to practice description which --

JUDGE SPIEGEL: Would you point me to that please?

MR. GOLDSTEIN: Sure. I would be happy to. I don't have the first ~~party~~ priority document in front of me, but I can find it for you, and I promise I'll get back to --

JUDGE SPIEGEL: How about if we give you two extra minutes at the end of your rebuttal?

MR. GOLDSTEIN: I will give you page and

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line as to where antibodies are fully described. Now, there is no --

JUDGE SPIEGEL: The subject matter of the count --

MR. GOLDSTEIN: Yes.

JUDGE SPIEGEL: -- not a piece here and a piece there?

MR. GOLDSTEIN: Yes. The subject matter of the count is in -- is in our priority document; and, while there is no actual reduction to practice of an antibody in this April 6 patent application, that is by no means ~~failed~~ fatal. I bring the ~~board's~~ Board's attention to the very recent case of Falkner v Inglis, which is slip opinion ~~051324~~ 05-1324 decided in May of 2006. ~~Faulkner~~ Falkner is a case from the ~~federal~~ Federal ~~circuit~~ Circuit dealing with pox viruses and herpes viruses. And in ~~Faulkner~~ Falkner the ~~federal~~ Federal ~~circuit~~ Circuit indicated very clearly that you don't need to have an actual reduction in practice in order to comply with 112 first paragraph in the description.

JUDGE SPIEGEL: So, what you're saying is

that in your earlier applications you have a constructive description of a monoclonal antibody that specifically binds to the DR5 --

MR. GOLDSTEIN: Yes.

JUDGE SPIEGEL: -- as identified by --

JUDGE SCHAFER: As I remember, all of your -- all of your prior documents do describe the DR5 sequence --

MR. GOLDSTEIN: Yes.

JUDGE SCHAFER: -- is that correct?

MR. GOLDSTEIN: And -- and yes, and the domains, correct.

JUDGE SCHAFER: The sequence that's in the count is --

MR. GOLDSTEIN: Yes, Your Honor. So, we have a constructive reduction of practice. Now, what does -- what does Party Adams say about this? They -- their position ultimately comes down to the fact that because in their 119 case they have actually made an antibody, this 3F11 antibody, that you need to have an actual reduction to practice.

Now, this is contradicted by positions parallel that they took earlier on when in this ~~priority~~ prosecution they were trying to get allowance for involved claims essentially to these antibodies. They had a 131 affidavit by their inventor, Dr. Ashkenazi -- and I bring your attention to tab three of my demonstrative exhibits where at paragraphs six and nine of his 131 affidavit Dr. Ashkenazi says that the 216 application, which is an identical application filed on the same day as the 615, he had full conception and constructive reduction to practice of an antibody, an agonistic antibody.

It was not until the 119 case that they actually made one, but early on before this interference was declared Ashkenazi was very happy to swear under oath that he had a constructive reduction to practice. They changed their tune after they realized that perhaps they could make an argument that they had made one here, even though -- not earlier and we hadn't made one until later, but that's only an argument of convenience.

The other thing that contradicts this actual reduction to practice theory of our opponents in addition to ~~Faulkner~~ Falkner is that -- and I bring the ~~board's~~ Board's attention to tab five. This is a portion of the cross-examination of their expert, Dr. Karin, in which Dr. Karin applied his extrinsic post-interference definition and count construction of what an agonist is and what an antagonist is, which contradicts the intrinsic definitions in the specs of the parties.

But, again, because of convenience, Karin defines an agonist as necessarily being limited to a molecule that competes with a ~~cognant~~ cognate ligand and that you need to know the ~~cognant~~ cognate ligand and you need to mimic physiologically relevant conditions. And, with this definition I asked him -- after I took him through the Genentech priority documents -- does Genentech have an agonist antibody, are they entitled to call their antibody an agonist antibody? And he said -- and you can read it right here. He said no.

This is part of our request to file a

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supplemental opposition, Your Honor. And you -- if I may refresh your memory, you said that we would address this ~~as~~ at oral hearing.

JUDGE SCHAFER: Yes.

MR. GOLDSTEIN: We believe that during the cross-examination of their expert, there's highly-relevant testimony that came up that concerns their view that they have an actual reduction to practice. Well, it turns out under this post-interference definition of Genentech and Dr. Karin they don't -- and Karin's own testimony they don't have an actual reduction to practice.

So, where does that leave the parties? Well, as far as Genentech is concerned, Karin's testimony says that they don't have an actual reduction to practice here, and they have requested benefit for their '615 application sort of in a piggyback way, saying, if you give it to us [HGS], give it to them [Genentech], too.

And, if you read it, you will see that they don't have a prima ~~facia~~ facie case. In fact, Dr. Karin testified just like Dr. Reed testified

that if you want to know whether you've got an agonist antibody, you just test it. And that is, in fact, found at tab four, page two where I asked Dr. Karin on cross whether if you made a set of monoclonal antibodies and you wanted to know which ones were agonist and which ones were antagonist wouldn't you just test them.

And he said, if that's what you want. And I said, a person of skill in '97 would have done that, too, right. And he said, I believe so. So, the fact that we didn't have a reduction -- an actual reduction to practice does not, in any way, detract from the fact that ~~he~~ we fully enabled, described and provided a credible utility for the production and verification of agonistic and antagonistic antibodies.

JUDGE SPIEGEL: Let me stop you one second here. So, you don't have an actual reduction to practice set forth in those earlier applications? Do you have an anticipatory constructive reduction --

MR. GOLDSTEIN: Yes, I do, Your Honor.

JUDGE SPIEGEL: And that's what you're going to give me?

MR. GOLDSTEIN: Yes.

JUDGE SPIEGEL: Okay. And, if we were to decide to allow the supplemental response, does that mean you are -- you would be withdrawing your motion to exclude from evidence the Karin cross-examination?

MR. GOLDSTEIN: No. I have not moved to exclude from evidence the Karin cross-examination. I have moved to exclude from evidence the Karin redirect examination, not the cross-examination. The redirect examination of Dr. Karin was chock full of leading questions to which we object --

JUDGE SPIEGEL: Yes or no is fine because you're coming up on your time --

MR. GOLDSTEIN: I'm sorry?

JUDGE SPIEGEL: Yes or no is fine.

MR. GOLDSTEIN: Okay, okay. I believe I may have another minute or two. I wanted to raise one last point about this parallel prosecution. We have filed a motion for sanctions against

Genentech on the basis that on May 15th they filed identical patent applications. On February 9, 1998, they filed identical patent applications. They use the '746 patent application, which is this middle purple box when they have claims that where -- involved in the -- that -- there are claims that are involved that correspond to the count.

The examiner in their middle case here was Claire Kaufman. It was the same examiner that was examining our '009 patent application, and they submitted a series of -- essentially what amounted to pre-~~ground~~ grant oppositions against our case in their own case essentially protesting the allowance and issuance of any claim --

JUDGE ~~SPRIGGS~~ SCHAFER: Okay. Assuming all of that stuff you say is true --

MR. GOLDSTEIN: Yes.

JUDGE SCHAFER: -- and we assume that, why do we have jurisdiction to sanction somebody for something that was done in a proceeding that was not before us?

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MR. GOLDSTEIN: Well, the ~~board~~ Board has jurisdiction over actions that have occurred ex parte in claims that involved in this interference --

JUDGE ~~CRIDGEN~~ SCHAFER: Why do you we have jurisdiction --

MR. GOLDSTEIN: Well, for example -- the board took jurisdiction, for example, in Norton v Curtis and Langer v. Kaufman and in other cases where inequitable procurement, for example, was committed ex parte in a case that led to an interference, and the ~~board~~ Board then took jurisdiction and was able to decide or not to decide on sanctions.

But these are clearly claims of Genentech that were involved. They, in fact, admitted -- and I have a demo exhibit that -- that the claims were to the same subject matter. When our case was allowed by Examiner Kaufman and they were following this on PAIR, they filed in '05 another protest, another complaint. The main point here that they were trying to accomplish was to prevent

HGS from getting a patent. They wanted the patent first, but do they ever request an interference? Did they ever use rule 202? No.

The only thing they wanted in filing these papers in their own case was to prevent us from getting a patent, and I don't think that the ~~board~~ Board should avoid taking jurisdiction over this and I don't think that the ~~board~~ Board should condone this behavior.

It is, in fact, inappropriate behavior, and it's important to the bar that you send a very strong signal because this sort of thing happens all the time. Not what Genentech has done, but the fact that people follow their competitors' patent applications now on PAIR and realize what's going on and when allowances come out, the temptation to file these papers quote in your own case when you know that it's the same examiner is very high.

JUDGE SCHAFER: Well, what would be the effect -- what if they just said, hey, we know about this application pending; we can see the

spec; we see there's some information that might be relevant; and, here's our 131 affidavit to show that what we did and what we claim we did before?

MR. GOLDSTEIN: Well, Judge Schafer, with all due respect --

JUDGE SPIEGEL: Is that what we have here or is that --

MR. GOLDSTEIN: No.

JUDGE SPIEGEL: -- or is it beyond that?

MR. GOLDSTEIN: Beyond that.

JUDGE SCHAFER: So, it's not just saying we -- in your view, it's not just --

MR. GOLDSTEIN: That's correct.

JUDGE SCHAFER: -- we did this invention earlier, Examiner, so this should never come up as an issue against us, but because we're anticipating --

MR. GOLDSTEIN: This was not just an in re Wertheim ~~regard hand~~ discussion (sic), and it was not a 131. There was a January 2003 so-called 131, which, if you look at it, is not a 131. It's a -- it's a 22-paragraph so-called 131 that has nothing

but attacks on enablement, written description and utility of our case.

**JUDGE** SCHAFER: Well, wouldn't it be isn't it fair, though, when you say this could be a potential reference because -- and I'm going to tell you why this is isn't -- why this isn't a reference for me. Because they have an earlier document, which they need the date of it, and it does not enable the invention that I -- you can give a 102, a **102(b)** reference -- looks like a **102(b)**, and you can show evidence that it really doesn't enable the -- the subject matter relied on in the reference really isn't an enablement and then put in proofs and affidavits to that effect?

MR. GOLDSTEIN: Right,

**JUDGE** SCHAFER: Can -- can't you do that in the context of **131?** I think that might be a misnomer under that circumstance. That would re

# EXHIBIT 13

United States Patent and Trademark Office

Before the Board of Patent Appeals and Interferences
(Interference Trial Section)

13 September 2004

# STANDING ORDER

This Order is promulgated by and for the Trial Section under Bd. R. 104 for use in contested cases.

## CONTENTS

**¶ 1 Notice of confidential information**

Some opinions are selected for publication to promote public understanding of Trial Section practice or to create uniform practices. If a party believes that its application contains information not otherwise publicly available that should be redacted from any opinion, the party must **within two (2) months** of the initiation of the contested case file as a separate paper a notice specifically identifying such information.

If additional information not otherwise publicly available is introduced into a contested case that a party believes should be redacted from any opinion, the party must promptly file a notice specifically identifying the information.

If, after filing such notice, specifically identified information becomes publicly available (for example, through publication of a collateral application), the party shall promptly notify the Board of this change in the status of the information.

**¶ 2 Record management**

**¶ 2.1 Letters between counsel not to be filed**

No letter between counsel may be filed unless it is filed as an exhibit cited in a motion, opposition, or reply, or during cross-examination.

**¶ 2.2 No duplicate papers**

A party may not file (not even as an appendix or exhibit) a copy of a paper previously filed in the same contested case.

**¶ 3 Mandatory notices**

**¶ 3.1 Real party-in-interest**

Within **fourteen (14) days** of the date of the Declaration, each party must file as a separate paper a notice of any and all right, title, or interest in any application or patent involved in the contested case.

**¶ 3.2 Related proceedings**

Within **fourteen (14) days** of the initiation of a contested case, each party must file and serve as a separate paper a notice identifying the application or patent number of every United States application or patent claiming, or which may claim, the benefit of priority of the filing date of the party's involved patent or application. If there are no such applications or patents the notice must state this fact. If, during the course of the proceeding, a party files an application claiming, or which may claim, the benefit of the filing date of an involved application or patent, a notice of the filing, including the application number, must be promptly served and filed.

**¶ 4 Communications with the Board**

**¶ 4.1 Default mode**

Mail is the default mode of communication.

**¶ 4.2 Filing by hand**

Hand delivery to the Board must occur between the hours of 8:30 a.m. and 5:00 p.m at:[*]

Madison Building East, 9th Floor
600 Dulany Street
Alexandria, Virginia 22314

Any paper hand-delivered directly to the Board before 10:00 a.m. is deemed to have been filed the previous business day provided the paper was properly served the previous business day.

**¶ 4.3 Overnight delivery services**

Papers filed using an overnight delivery service must be addressed:[**]

---

* Prior to 6 October 2004, deliver to Crystal Gateway Two, Floor 10, 1225 South Clark Street, Arlington, Virginia.

** Prior to 6 October 2004, use Board of Patent Appeals and Interferences, Crystal Gateway Two, Floor 10, 1225 South Clark Street, Arlington, Virginia.

Board of Patent Appeals and Interferences
Madison Building East, 9th Floor
600 Dulany Street
Alexandria, Virginia 22314

Properly addressed papers filed are deemed filed on the date they are delivered to the overnight delivery service.

**¶ 4.4 Telephone calls**

Telephone calls to the Board regarding a contested case must be placed to 571-272-9797.[*] A telephone call requesting a conference call must be directed to Trial Section support staff.

**¶ 4.5 Facsimile**

The facsimile number for contested cases is 571-273-0042.[**] Do not send papers exceeding five (5) pages in length without prior permission from Trial Section support staff.

**¶ 5 Copies of authority cited**

If a party files a paper citing an authority that is not reported in (1) United States Reports or West Publishing Company's Supreme Court Reporter, (2) the second or third series of West's Federal Reports, or (3) the first or second series of the Bureau of National Affairs' United States Patents Quarterly, then the party must file and serve a copy of the authority.

**¶ 6 Modification of the Standing Order**

An administrative patent judge may modify the terms of this Order.

**¶ 7 Paper format**

**¶ 7.1 Footnotes**

The use of footnotes is discouraged. Footnotes must be double-spaced.

---

* Prior to 6 October 2004, use 703-308-9797.

** Prior to 6 October 2004, use 703-305-0942.

**¶ 7.2 Cover sheet for papers other than exhibits**

**¶ 7.2.1 Caption**

The heading shown in Part G of the Declaration shall be used in all papers other than exhibits. Form **1** in the Appendix of Forms shows a standard caption for an interference.

**¶ 7.2.2 Style**

The style of each paper must appear on a single line and must not use the words "et al". Styles for papers other than motions, oppositions, and replies should be simple and descriptive.

**¶ 7.2.3 Color of cover sheet**

The first page of all papers filed in an contested case must be **pink** similar to the pink first page of the Declaration.

**¶ 7.3 Combined oppositions and replies not to be filed**

An opposition shall respond to only a single motion and a reply shall respond to only a single opposition.

**¶ 7.4 Copy for the administrative patent judge**

A party must file (1) an original and (2) a copy of each paper filed. The copy shall be marked at the top:

APJ COPY

**¶ 8 Papers in electronic form**

**¶ 8.1 Only a copy of a paper may be filed in electronic form**

Parties may file a copy of a paper in electronic form. (A facsimile is not a paper in electronic form.) The required number of paper copies must also be filed with the Board and served on all opponents.

**¶ 8.2 Format**

The Board can accept electronic copies in the following PC-compatible media:

A compact disc,

3¼ inch diskette,

A 100 MB Zip® disk, or

A 2 GB Jaz® disk.

The electronic copy must be capable of:

(a) Operating on a computer running WINDOWS XP.

(b) Displaying on a monitor set to display at 256 colors on an 800 x 600 pixel screen setting.

(c) Opening and being word searched in ADOBE ACROBAT READER, WORDPERFECT 9, or MICROSOFT WORD 2000. Parties use other formats at their own risk.

The file name of each electronic document must concisely identify the content of the document (e.g., Jones PM1.wpd, Smith Opp1.doc; Ex1038.pdf). If a hearing is requested, four copies of the electronic media should be filed with the Board and one copy served on each opponent.

**¶ 9 Service**

**¶ 9.1 Alternatives to EXPRESS MAIL®**

Any other mode of service that accomplishes a same-day or overnight delivery of the paper (e.g., by hand, facsimile, or a commercial overnight delivery service) may be substituted for EXPRESS MAIL® service.

**¶ 9.2 Papers served but not filed**

The following papers must be served on an opponent, but should not be filed with the Board at the time of service:

(a) An objection to the admissibility of evidence.

(b) A notice requesting cross-examination.

(c) Automatic discovery pursuant to Bd. R. 150(b)(1).

Such papers may be filed later as an exhibit if a dispute arises with respect to the paper served.

**¶ 9.3 Transmittal sheets**

Do not file a transmittal sheet listing papers being filed except an exhibit list may be filed when more than one exhibit is being filed.

**¶ 10 Lead and backup counsel**

The notice identifying counsel under Bd. R. 108(b) must identify both a lead counsel and a backup lead counsel, and must provide for each the contact information specified in Bd. R. 108(b)(1)-(b)(5).

If lead counsel or backup counsel are not counsel of record (37 CFR § 1.34(b)) in the involved application or patent, then a power of attorney must be filed with the Board for entry in the involved patent or application file within the **fourteen (14) day** period of Bd. R. 108(b).

**¶ 11 Request for file copies**

A party seeking copies of an involved or benefit file mentioned in the Declaration must, within **fourteen (14) days** of the date of the Declaration, file with the Board (not another part of the Office) a separate paper styled [Name of party] REQUEST FOR FILE COPIES to which is attached a completed FILE COPY REQUEST. See Form **4** in the Appendix of Forms.

**¶ 12 Later presented or contested claims**

If a party moves to involve a new (or uninvolved) claim in the contested case, the movant must comply with the requirements of Bd. R. 110(a) and (b) for the new claim.

**¶ 13 Motions**

**¶ 13.1 Numbering motions**

Each motion of each party must be numbered consecutively, starting with one, regardless of the type of motion.

## 113.2 Page limits in motions

A motion is limited to twenty-five **(25)** pages, not including a table of c

# EXHIBIT 14

Paper 115
6/19/07

Filed on behalf of: Party Ni
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)

Human Genome Sciences, Inc.
Junior Party
(Application 10/005,842-IFW;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu and Craig A. Rosen),

v.

Immunex Corp.
Senior Party
(Patent 6,642,358;
Inventors: Charles Rauch and Henning Walczak).

Patent Interference No. 105,381 (RES)

**NI RESPONSE TO ORDER TO SHOW CAUSE**

Pursuant to the Board's Order to Show Cause -- Bd.R. 202(d), filed 1 June 2007 (Paper 114) ("Order"), Party Ni respectfully submits the following Response.

## *I. Statement Regarding Precise Relief Requested*

The Board noted in the Order that "all of Human Genome Sciences (HGS) involved claims were held to be unpatentable under 35 U.S.C. § 102(e)." (Order, p. 1.) The Board therefore stated that "[a]s HGS is the junior party and has no patentable claims, there does not appear to be a reason to continue this interference into the priority phase." (Order, p. 1-2.) For the reasons set forth below, Party Ni respectfully disagrees with the Board's conclusion and requests that the above captioned interference proceed to the priority phase.

## *II. Exhibits and Statement of Material Facts*

A list of exhibits relied upon herein is attached hereto as Appendix A. A statement of Material Facts supporting this Response is attached hereto as Appendix B.

## *III. The Board is Statutorily Obligated to Determine the Outstanding Question of Priority of Invention in This Interference*

The above captioned interference was properly declared and commenced by the Board. Party Ni thus has standing to pursue the interference and the Board's determination that Party Ni's involved claims are unpatentable under 35 U.S.C. § 102(e) is not a threshold issue that deprives Party Ni of its standing. Party Ni has not waived its right to enter the priority phase and has proffered sufficient evidence to merit full consideration of priority. For these reasons, the Board is statutorily obligated to determine the priority of invention in this interference.

### *A. The Board is Statutorily Obligated Resolve Fairly and Fully Raised Priority Questions*

The Board's obligation to determine fully and fairly raised questions of priority is well settled. The obligation is grounded in the plain language of the statute and fully supported by both Federal Circuit and Board decisions.

### *1. The Plain Language of the Statute Clearly Sets Forth the Board's Obligation to Determine Questions of Priority*

A plain reading of 35 U.S.C. § 135(a) indicates that after an interference is declared, the Board is obligated to determine the priority of invention. Section 135(a) states in relevant part that "[t]he Board of Patent Appeals and Interferences *shall* determine questions of priority of the inventions and *may* determine questions of patentability." 35 U.S.C. § 135(a) (2004) (emphasis added). While the Board in this case has ruled on the question of patentability of Party Ni's involved claims under 35 U.S.C. § 102(e), the question of priority of invention remains unresolved. The Board is therefore statutorily obligated to continue with the priority phase. As illustrated below, continuation to the priority phase in this interference is fully consistent with the statute and its underlying public policy that all issues that are fully and fairly raised during an interference proceeding should be decided by the Board.

### *2. The Federal Circuit and the Board have Broadly Interpreted the Statute as a Strong Mandate to the Board to Determine All Issues Fairly Raised in an Interference*

In *Perkins v. Kwon*, 886 F.2d 325, 12 USPQ2d 1308 (Fed. Cir. 1989) the Federal Circuit examined the new interference rules that enabled the nascent BPAI to decide both patentability and priority issues. In *Perkins*, the Board determined that Kwon, the junior party, was the prior inventor and cancelled the claims of Perkins. However, the Board also found that the count was unpatentable to Kwon because of an on-sale bar under 35 U.S.C. § 102(b). On appeal, Perkins challenged the Board's authority to decide the question of priority although it determined that Kwon's claims were unpatentable. The Federal Circuit determined that the Board was essentially obligated to decide the priority issue even after it determined that Kwon's interfering claims were unpatentable.

The court stated that it would contradict the remedial purpose of the legislation "if the Board were to refrain from deciding priority, when the result of such restraint would be the issuance or preservation of a facially invalid patent. " *Id.* 886 F.2d at 328, 12 USPQ2d at 311. Going further, the court stated that:

> The Board, by resolving both priority and patentability when these questions are fully presented, settles not only the rights between the parties but also the rights of concern to the public. The public interest in the benefits of a patent system is best met by procedures that resolve administratively questions affecting patent validity that arise before the PTO. To do otherwise is contrary to the PTO's mission to grant presumptively valid patents, 35 U.S.C. § 282, and thus disserves the public interest.

*Id.* The court in *Perkins* thus broadly interpreted the new statute as a mandate to the Board to resolve fully and fairly raised issues concerning priority in a properly declared interference.

This broad interpretation was confirmed by the Federal Circuit ten years later in *Rexam Indus. Corp. v. Eastman Kodak Co.*, 182 F.3d 1366, 51 USPQ2d 1457 (Fed. Cir. 1999), wherein the court stated that "[w]e have consistently applied the rationale of *Perkins* to conclude that *priority issues that have been fully developed and presented to the Board for decision in interference proceedings should be decided by the Board even if a count is deemed unpatentable to one party.*" *Rexam Indus.*, 182 F.3d at 1369, 51 USPQ2d at 1459 (emphasis added). In *Rexam Indus.*, the Federal Circuit pointed to the "statutory policy of deciding all properly raised issues" when it permitted Kodak to pursue its priority claim in an action under 35 U.S.C. § 146, despite the fact that Kodak had no patentable claims remaining in the interference.

The Board has also adopted a broad reading of *Perkins*. For example, in *Short v. Punnonen*, 82 USPQ2d 1382 (BPAI 2006) (non-precedential), junior party Short elected not to file a priority motion, apparently believing that the alleged unpatentability of Punonnen's sole involved claim was a threshold issue that, if decided in Short's favor, would dissolve the

interference. The Board firmly disagreed. Citing the Federal Circuit's decision in *Perkins*, the Board noted that even if Punnonen did not have any patentable claims, "[i]t would … contradict the legislative purpose if the Board were to refrain from deciding priority, when the result of such restraint would be the issuance or preservation of a facially invalid patent." *Id.* (citing *Perkins*, 886 F.2d at 328, 12 USPQ2d at 1311). The Board concluded by stating that "*both the relevant rules and the case law contradict Short's proposition that a decision of unpatentability under 35 U.S.C. § 102 or 103 necessarily moots the priority contest.*" *Id.* (emphasis added).

Despite the fact that Short had explicitly declined to enter the priority phase, the Board nonetheless ordered Short to address its obligation to file a priority motion. The Board thus recognized the primacy of determining questions of priority in an interference, regardless of the unpatentability of one of the party's claims. Because the issue of priority in this interference remains similarly unresolved, the Board cannot avoid its statutory obligation to determine priority of invention.

### *B. Only in Very Narrow Circumstances Has the Board Refused to Resolve Outstanding Questions of Priority*

As discussed below, the Board has refused to determine outstanding questions of priority of invention only in very narrow circumstances, none of which are present in this interference. One instance is where a threshold issue has been resolved in favor of a movant, thereby depriving a party of standing in the interference. A second circumstance is where a party has waived its right to continue to the priority phase by electing to swear behind a reference under 37 C.F.R. § 1.131 during the motions phase. Finally, the Board has refused to determine priority where it finds no sufficient justification to subject a party with patentable claims to the expenses of time and resources required for a priority case.

### *1. Patentability Under 35 U.S.C. § 102(e) is Not a Threshold Issue That Deprives a Party of Standing in an Interference*

The Board's determination that Party Ni's involved claims are unpatentable over prior art under 35 U.S.C. § 102(e) is not a threshold issue that deprives Party Ni of standing in this interference. This conclusion follows ineluctably from the rules as well as from Federal Circuit and Board decisions. The current regulations narrowly define "threshold issue" as "an issue that, if resolved in favor of the movant, would deprive the opponent of standing in the interference." 37 C.F.R. § 41.201 (2006). The rules further identify several such "threshold issues" including no interference-in-fact, repose under 35 U.S.C. § 135(b), and unpatentability for lack of written description. *Id.* Unpatentability over prior art is not one of the enumerated threshold issues.

The Federal Circuit has made it clear that unpatentability in view of prior art is not a "threshold issue." For example, in *Berman v. Housey*, 291 F.3d 1345, 63 USPQ2d 1023 (Fed. Cir. 2002), the court identified Housey's motion under 135(b) as involving a "threshold issue," and distinguished Berman's motion for unpatentability in view of the prior art as a "garden-variety patentability issue." *Berman*, 291 F.3d at 1352, 63 USPQ2d at 1028. Similarly, in *Wu v. Wang*, 129 F.3d 1237, 44 USPQ2d 1641 (Fed. Cir. 1997), the Federal Circuit stated that "[d]espite having lost the right to his patent as a result of an adverse decision on patentability, Wang still had an interest in seeing that Wu was likewise not entitled to the subject matter of the interference, albeit on patentability, not priority, grounds." *Wu*, 129 F.3d at 1241, 44 USPQ2d at 1644-45. *Berman* and *Wu* thus clearly establish that an adverse decision on patentability is not, by itself, a threshold issue that deprives a party of standing in an interference.

Consistent with *Berman* and *Wu*, the Board has determined priority in a number of cases in which a party was left with no patentable claims. In a 2003 decision, the Board decided to continue with the priority phase of an interference despite the fact that all of one party's claims

had been deemed unpatentable under 35 U.S.C. § 112(1) for failure to set forth the best mode. *Tannas v. Watson*, 73 USPQ2d 1382 (BPAI 2004) (non-precedential). Therein, the Board stated that:

> Interferences are declared to assist the examiner in making a determination of whether an involved application should issue as a patent, e.g., to resolve the issue of priority. Here the issue of priority has not been resolved. *That Tannas has no patentable claims based on a best mode violation does not assist the examiner in determining whether the Watson claims that correspond to the count are patentable under 35 U.S.C. § 102(g).* Thus, we exercise our discretion and continue this interference to determine priority of invention.

*Tannas*, 73 USPQ2d at 1384. *Tannas* indicates that properly declared interferences are supposed to resolve issues of priority. Thus, if an interference is properly declared, the Board should not terminate it in advance of resolving the issue of priority, even when one party is left with no patentable claims. In the present interference, a determination that Party Ni has no patentable claims under § 102(e) does not assist the Board in determining whether Party Rauch was entitled to its involved claims under 35 U.S.C. § 102(g) -- *i.e.*, patentability under § 102(e) is not a threshold issue.

The Board's recent decision in *Short* (discussed above) further confirms that patentability over prior art is not a threshold issue. Therein, junior party Short elected not to file a priority motion, apparently believing that the alleged unpatentability of Punonnen's sole involved claim was a threshold issue upon which the interference could be resolved and dissolved. *Short,* 83 USPQ2d at 1383. The Board firmly disagreed, stating that "*there is scant authority for the proposition that any patentability question by itself is a threshold issue.*" *Id.* (emphasis added). Despite the fact that Short believed that Punonnen's sole claim was unpatentable, the Board nonetheless ordered Short address its obligation to file a priority motion. The Board ultimately concluded that "the implication of the rules is that it takes more than mere unpatentability to

establish a threshold issue" and that "[i]t would be entirely possible for the Board to determine that Short loses on priority even if Punnonen loses on patentability." *Id.*

In this interference, the Board determined that all Party Ni's involved claims are unpatentable under 35 U.S.C. § 102(e). (Order, p. 1.) The statute, rules and above cases make it clear that the Board's unpatentability decision is not a threshold issue that deprives Party Ni of standing in this interference. Party Ni and the public therefore retain the right to see that the priority issue relating to the subject matter of the interference is resolved.

### *2. Party Ni has Not Waived its Right to Continue to the Priority Phase in This Interference*

The statute, rule and case law discussed herein evince only one circumstance in which a party may waive its right to proceed to the priority phase of an interference based on an unpatentability decision during the preliminary motions phase. More specifically, if a party elects to rebut a motion for unpatentability under 35 U.S.C. §§ 102(a) or (e) by antedating the applied reference under 37 C.F.R. § 1.131, then that party may have waived its rights to proceed to the priority phase. That circumstance is explained in the Board's decisions *LeVeen v. Edwards*, 57 USPQ2d 1416 (BPAI 2000) and in *Navarrini v. Worm*, 79 USPQ2d 1178 (2005). In those cases, the Board noted the similarities of proofs in antedating a reference under 37 C.F.R. § 1.131 and establishing priority. As the Board stated in *Navarrini*, "if a party elects … to put on a rule 131 showing and fails, it generally will have waived any opportunity to get a second bite at the apple in the priority phase." *Navarrini*, 79 USPQ2d at 1181.

Party Ni made no similar attempt to antedate the asserted reference under Rule 131. Rather, Party Ni attempted to defeat Party Rauch's motion for unpatentability under § 102(e) by asserting that it should be accorded the filing date of its own earlier filed related application under §§ 119 or 120. (Decision - Rehearing - Bd.R. 125(c), Paper 113, p. 3.) The Board

explicitly acknowledged in its Decision on Party Ni's request for Rehearing that "[u]nlike antedating under § 1.131 and priority, which involve similar considerations, there are no readily apparent similarities between proofs and arguments attempting to establish an earlier effective filing date, on the one hand, and priority proofs and arguments, on the other." (*Id.* p. 7.) Therefore, following the logic of *LeVeen* and *Navarrini*, Party Ni's decision to oppose Party Rauch's unpatentability motion under § 102(e) by asserting the priority date of its earlier filed application was properly asserted in the motions phase of this interference because of the similar proofs required, for example, in Party Ni's benefit motions. By choosing to rebut Party Rauch's motion for unpatentability in this fashion, Party Ni has in no way waived its right to proceed to the priority phase of this interference.

### 3. *Party Ni has Established Sufficient Justification for the Board to Continue to the Priority Phase of This Interference*

In *Noelle v. Armitage*, 2003 Pat. App. LEXIS 21 (2003) (non-precedential), the Board terminated an interference in the absence of a threshold issue, before making a priority determination. Therein, the Board found that Noelle's claims were unpatentable under 35 U.S.C. § 112(1) for lack of enablement. However, because neither party had copied claims, the Board stated that "[t]his circumstance … largely removes the decision for lack of enablement as an equivalent to a 'threshold issue.'" *Noelle*, at *20. The Board nonetheless terminated the interference because the "cumulative weight of the factors in this proceeding" were insufficient to justify continuation with the interference. *Id.* at *22.

More specifically, the Board found that Noelle made no attempt to add claims that were supported by its application and that interfered with Armitage's claims; nor did Noelle seek to redefine the count in an effort to define claims that would be supported by its application. Additionally, the Board found that "the scant and debatable evidence supporting Noelle's prior

invention developed thus far weighs against a holding that priority has been fully and fairly raised." *Id.*, at *22. Indeed, in denying Noelle's motion for reconsideration, the Board stated that "if the record thus far developed contained a compelling reason to doubt Armitage's priority, we might have exercised our discretion differently." *Id.*, at *31-32. The Board therefore terminated the interference and entered final judgment against Noelle because it believed that, while a threshold issue had not been raised, Noelle had not presented sufficient justification for continuing with the interference. Finally, the Board made it clear that its decision in *Noelle* should be restricted to its facts stating that "[w]e expressly declined to use this case as a vehicle to pronounce broad interpretations of the law or our procedures" *id.* at *25, and that "each case must be decided on its particular facts." *Id.*, at *22.

This interference is distinguishable on the facts from *Noelle* in several ways. First, the character of the § 112 first paragraph rejection in *Noelle* for enablement directly calls into question a party's right to continue in an interference. Indeed, PTO considered adding enablement to the list of threshold issues. It refrained, however, stating that "[s]ince the list of threshold issues is inclusive, it would permit additional issues to be treated as standing issues. Whether enablement is routinely such an issue is left to further development through adjudication." Notice and Comment, 69 FR 49960, 49991 (Aug. 12, 2004). The unpatentability of Party Ni's involved claims under § 102(e), on the other hand, is of an entirely different character because an adverse decision would not implicate a party's standing or its ability to prevail in the priority phase.

Second, the Board noted that one factor weighing against Noelle was that it made no effort to add claims that were supported by its specification, or to redefine the count. Party Ni, unlike Noelle, sought to redefine the count during the motions phase. More specifically, Party

Ni sought to amend the count from a polypeptide that binds TRAIL to a polypeptide that binds TRAIL or induces apoptosis. (Fact 513.) This is significant because the Board's refusal to redefine the count may have directly impacted Party Ni's ability to rely on its earlier filed application under §§ 119 or 120, and defeat Party Rauch's motion for unpatentability under § 102(e). This factor thus weighs in favor of Party Ni.

Third, at this stage of the proceedings, Party Ni has made a showing for its priority case far beyond that presented by Noelle. At the outset, Party Ni's Priority Statement constitutes a proffer sufficient to continue with the interference. *See Tannas*, 73 USPQ2d at 1383-84 (distinguishing *Noelle* and noting that Tannas was "not required to provide its priority evidence during the preliminary phase, and thus Watson's arguments that Tannas has failed to provide any evidence of corroboration of conception, diligence, or lack of concealment or suppression is without merit."). Party Ni's Priority Statement alleges an earliest corroborated date on which Ni's conception occurred and diligence began as December 2, 1996, which is before Rauch's earliest accorded benefit date of March 28, 1997. (Fact 514.)

In addition to its Priority Statement, Party Ni informed the Board of the substance of its priority case during a conference call on April 3, 2007. (Fact 515.) Additionally, Party Ni submitted on May 10, 2007, its Miscellaneous Motion 6 Requesting Authorization for Compulsion of Testimony and Production. (Fact 516.) Therein, Party Ni further informed the Board of the basis for its priority case. (Fact 516.) Finally, in the present Response to the Board's Order to Show Cause, Party Ni illustrates below the strength of its priority case and casts great doubt as to whether Rauch is entitled to prevail on priority. Noelle apparently made no such showing. These facts weigh strongly in favor of the Board proceeding to the priority phase in this interference.

As a final matter, in the precedential decision *Winter v. Fujita*, 53 USPQ2d 1478 (BPAI 2000), the Board listed several other "circumstances where a decision on priority and a decision on patentability may not be appropriate." *Id.* at 1489. One example is "where a party files a preliminary motion for judgment based on no interference-in-fact." *Id.* In such instance, the absence of an interference-in-fact is clearly a threshold issue, and no interference should even be declared. 37 C.F.R. § 41.201 (2006). Another example is "where all the claims of *both* parties corresponding to the count are held to be unpatentable over the prior art." *Winter*, 53 USPQ2d at 1489 (emphasis added). Clearly, where neither party has patentable claims corresponding to the count, a determination of priority is unnecessary. Yet another example is "where a patentee can establish that an applicant derived an invention from the patentee." *Id.* In that case, the Board determined that "it may be inappropriate to let an applicant benefit from its 'less than good faith' by permitting an attack on the patentability of the claims in the patent." *Id.* None of the examples listed in *Winter* that might merit termination of an interference prior to the priority phase are present in this interference.

### *C. Conclusion--The Board is Statutorily Obligated to Determine the Outstanding Question of Priority of Invention in This Interference*

This interference was properly declared and commenced by the Board. Party Ni therefore has standing to continue the interference and the Board's determination that Party Ni's involved claims are unpatentable under 35 U.S.C. § 102(e) is not a threshold issue that deprives Party Ni of that standing. Party Ni has not waived its right to enter the priority phase and has proffered sufficient evidence to merit full consideration of priority. For these reasons, the Board is statutorily obligated to continue to the priority phase in this interference. As explained more fully below, Party Ni will prevail on the issue of priority.

## *IV. Party Ni Will Prevail on the Issue of Priority in this Interference*

As demonstrated herein, Party Ni will prevail on priority because Party Ni had an actual reduction to practice of an embodiment of Count 1 before Party Rauch's awarded benefit date of March 28, 1997. Alternatively, Party Ni will prevail on priority because Party Ni had a corroborated conception before Party Rauch's awarded benefit date, and Party Ni can demonstrate that it exercised diligence from just before Party Rauch's awarded benefit date until Party Ni's constructive reduction to practice. A showing in response to an Order to Show Cause under 37 C.F.R. § 202(e) "is not sufficient unless it would, if unrebutted, support a determination of priority in favor of the party making the showing." Party Ni well exceeds that requirement.

Party Ni had an actual reduction to practice of an embodiment of Count 1 by March 25, 1997, which is prior to Party Rauch's awarded benefit date of March 28, 1997. Alternatively, Party Ni had a complete corroborated conception of an embodiment within Count 1 by March 10, 1997. In the alternative, Party Ni demonstrates below that it had a complete corroborated conception by March 20, 1997 or by March 25, 1997. In the alternative, Party Ni demonstrates below that it worked diligently to reduce to practice an embodiment of Count 1 from just prior to Party Rauch's awarded benefit date on March 28, 1997, until the filing of HGS' U.S. Application No. 60/054,021 on July 29, 1997, which application constitutes a constructive reduction to practice of at least one embodiment of Count 1.

### *A. Party Ni Had a Corroborated Prior Complete Conception of the Invention of Count 1*

#### *1. Count 1*

Count 1 is represented by claim 6 of Party Rauch's U.S. Patent No. 6,642,358 ("the '358 patent"). (Fact 3). Claim 6 (re-written in independent form with all the limitations of claim 5 from which it depends) is as follows:

> A purified TRAIL-R polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence presented in SEQ ID NO:2, wherein said polypeptide binds TRAIL.

(Fact 2). According to the '358 patent, SEQ ID NO:2 is the amino acid sequence of the full-length TRAIL-R protein (also known as, inter alia, TRAIL-Receptor 2/TRAIL-R2). (Fact 3).

As explained in detail below, Party Ni conceived of a polypeptide that meets every limitation of Count 1. Specifically, Party Ni conceived of a protein referred to as DR5, which inherently binds to TRAIL (hereinafter "polypeptide" and "protein" are used interchangeably). The amino acid sequence of DR5 is set forth in each of Ni's priority applications, as well as Ni's involved application, as SEQ ID NO:2 ("Ni's SEQ ID NO:2") (Facts 4-6), and is more than 90% identical to Rauch's SEQ ID NO:2. (Facts 7-8, 198-203, 208-213).

DR5 is a member of a group of proteins known as the Tumor Necrosis Factor Receptor (TNFR) family. Membership in the TNFR family has traditionally been based on the structural similarity of these proteins. (Fact 9). A subset of the TNFRs are known as death receptors, and they contain a structural motif known as a death domain. (Fact 10).

Conception is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Kridl v. McCormick*, 105 F.3d 1446, 1449, 41 U.S.P.Q.2d 1686, 1689 (Fed. Cir. 1997). To establish conception of a chemical compound the inventor has to conceive of a practical utility for the compound. See *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 U.S.P.Q. 453, 457-58 (CCPA 1974); *D'Amico v. Brown*, 155 U.S.P.Q. 534, 537-38 (Bd. Pat. Int'f 1967). Conception of a practical utility for a chemical compound requires only that the inventor had formed the idea of an intended use of the compound "in sufficiently final form that only the existence of ordinary

skill remained to reduce it to practice." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1231, 32 U.S.P.Q.2d 1915, 1922 (Fed. Cir. 1994).

As discussed below, Party Ni had a complete corroborated conception of at least one embodiment of Count 1 by March 10, 1997, by which time the inventors:

- Had extensive knowledge of prior art death receptors known as TNFR1, Fas and DR3 (Facts 11-46);
- Had developed a strategy for identifying novel death receptors and making agonistic and antagonistic monoclonal antibodies to these receptors, and had already discovered and characterized two additional novel death receptors known as DR3 and DR4 (Facts 11-46);
- Had cloned and identified the full-length DR5 DNA sequence (Ni SEQ ID NO:1) and had identified the DR5 amino acid sequence (Ni's SEQ ID NO:2), and recognized that the DNA and amino acid sequences would encode a functional death receptor (Facts 47-86);
- Had appreciated that DR5 was a novel death receptor based on the presence of canonical structural features of death receptors (repeated cysteine-rich domains in the extracellular domain, a transmembrane domain, and an intracellular domain containing a death domain) and the fact that DR5 has significant sequence homology to the four death receptors mentioned above (DR3, DR4, TNFR1 and Fas) (Facts 47-86);
- Had appreciated that DR5 would bind to TRAIL, based on (i) the significant sequence identity at the protein level that DR5 has to the related death receptor DR4, which binds

to TRAIL, and (ii) the fact that DR5 and DR4 share the same cysteine residues in the extracellular domain (Facts 47-86);

- Had a complete and stable idea as to how to make and use a purified DR5 protein, e.g., to produce a functional DR5 protein that binds to TRAIL, and how such DR5 protein could be used to make agonist and antagonist antibodies that bind to DR5 (Facts 87-98);

- Had a complete and stable idea that such agonistic and antagonistic antibodies could be used to induce or inhibit apoptosis, e.g., to treat cancer (agonists) or AIDS (antagonists), respectively (Facts 87-98);

- Had a complete and stable idea of how to use a soluble DR5 fusion protein to inhibit DR5 ligand binding (e.g., an immunoadhesin) (Facts 87-98); and

- Had recognized that immunoadhesins could be used to inhibit receptor function by inhibiting native ligand-receptor interactions. (Fact 87-98).

As an alternative to the complete corroborated conception date of March 10, 1997, Party Ni submits that it had a complete corroborated conception of an embodiment of Count 1 by March 20, 1997, by which time Party Ni had repeatedly asserted that DR5 binds to TRAIL. (Facts 99-103). As a further alternative, Party Ni submits that it had a complete corroborated conception of an embodiment of the count by March 25, 1997, by which time Party Ni had obtained experimental confirmation that DR5 (i) binds to the apoptosis-inducing ligand TRAIL and (ii) induces apoptosis. (Facts 112-114, 116-119, 121-130, 131-142, 441-442). In view of the complete and stable idea that Party Ni had by March 10, 1997 (or, alternatively, by March

20, 1997 or by March 25, 1997), only ordinary skill would have been needed to reduce the invention to practice, as it was thereafter to be applied in practice. (Facts 144-288).

A party seeking to prove conception through the oral testimony of an inventor must proffer evidence corroborating that testimony. See *Price v. Symsek*, 988 F.2d 1187, 1194, 26 U.S.P.Q.2d 1031, 1036 (Fed. Cir. 1993). Corroboration need not take any particular form. See *Kridl*, 105 F.3d at 1450, 41 U.S.P.Q.2d at 1689. Whether or not an inventor's testimony is adequately corroborated is determined by a "rule of reason" analysis in which "an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached." *Price*, 988 F.2d at 1195, 26 U.S.P.Q.2d at 1037.

As discussed further below, the inventors' conception of an embodiment of Count 1 by March 10, 1997 is corroborated by Robert Benson and Reinhard Ebner and by documentary evidence, which has been authenticated by Biegie Lee and Michael Fannon. (Facts 59, 75, 80, 82, 83, 85, 94, 95-98, 455- 479). The inventors' alternative conception by March 20, 1997 is further corroborated by additional documentary evidence, authenticated by Biegie Lee and Michael Fannon. (Facts 455-479). The March 20, 1997 alternative conception date could be further corroborated by Dr. Vishva Dixit (Fact 71); however, in order to obtain his testimony, the Board must compel it. (Fact 73). The alternative conception date of March 25, 1997 is still further corroborated by additional documentary evidence and by Bradley Lorimier. (Facts 444-445). The March 25, 1997 alternative conception date could be further corroborated by Dr. Guohua (James) Pan (Facts 112-114, 116-119, 121-130, 131-142, 441-442); however, in order to obtain his testimony, the Board must compel it. (Fact 73). The activities leading up to and including the date of conception are discussed in detail immediately below, and are summarized in Appendices C and D.

### 2. *The Inventors' Prior Knowledge and Experience with Respect to Death Receptors*

Prior to March 10, 1997, Party Ni had extensive knowledge of the death receptor literature, and therefore was aware that, like all members of the TNF receptor superfamily, death receptors contain an extracellular domain (ECD) with an evolutionarily conserved pattern of repeating cysteine-rich domains (CRDs), as well as a hydrophobic transmembrane domain. (Facts 11-13, 152, 204). Party Ni also understood that death receptors were unique among members of the TNF receptor superfamily in containing an evolutionarily conserved motif known as the death domain, which is located in the intracellular region of the receptor. (Facts 14-16, 151, 153, 156, 204). Physical aggregation of the death domains of death receptors TNFR1 and Fas was known to trigger a cascade of signaling events leading to a form of programmed cell death known as apoptosis. (Facts 17-18, 154, 179, 204).

Prior to March 10, 1997, Party Ni understood that apoptosis could be induced in cells using agonistic antibodies that bind to the ECD of death receptors, or by merely overexpressing these receptors in cells, even in the absence of the native ligand. (Facts 17-20, 155, 204). Indeed, antibodies and receptor overexpression models were used to characterize Fas and DR3 as death receptors even before their native ligands were discovered. (Facts 17-20). Party Ni was familiar with this body of literature well before their discovery of DR5. (Facts 17-20).

By March 10, 1997, Party Ni had developed a proven approach for identifying novel death receptors, an approach which took advantage of the inventors' knowledge of the death receptor literature, and their experience in analyzing genetic sequences. (Facts 184-187, 190-194). This approach involved careful analysis of partial DNA sequences, such as Expressed Sequence Tags (ESTs) found in public and proprietary databases, to identify the canonical structural motifs found in death receptors, namely: an ECD with conserved CRDs, a

transmembrane domain, and an intracellular death domain. (Facts 21, 184-187, 190-194). Party Ni also examined the partial DNA and amino acid sequences for homology with the known death receptors, with the expectation that sequence conservation predicts functional conservation. (Facts 21-22).

In the process of searching and analyzing DNA sequence information for novel death receptors, Party Ni's inventors routinely conferred with each other to discuss the ESTs identified in such searches and to decide which full-length sequences to pursue. (Facts 21-22). After identifying the most promising partial sequences, Party Ni screened cDNA libraries to identify clones containing a full-length coding region, and then obtained the entire nucleic acid and amino acid sequences of novel death receptors. (Facts 21-23).

By March 1996, Party Ni's approach had yielded the discovery of DR3, a then novel death receptor identified by Drs. Ni, Yu and Gentz. (Facts 24, 184-188, 204). In March 1996, HGS filed a patent application (U.S. Application No. 60/013,285) directed to DR3 (initially called Death Domain Containing Receptor, or DDCR) disclosing, among other things, that DR3 contains an ECD with CRDs, a transmembrane domain, and an intracellular death domain. (Facts 25-26, 28, 273-277, 204). In collaboration with Drs. Vishva Dixit at the University of Michigan, Drs. Ni, Yu and Gentz later confirmed that, like TNFR1 and Fas, overexpression of DR3 induces apoptosis, which is dependent on the presence of the intracellular death domain. (Facts 29-33, 188, 271-283, 204). The results of these studies were published in the peer-reviewed journal *Science* in November 1996. (Facts 27, 165-172, 181-189, 204).

Also by November 1996, Party Ni, in collaboration with Drs. Dixit and Pan, identified Death Receptor 4 (DR4), which today is also known as TRAIL Receptor-1 (TRAIL-R1). (Facts 34, 190-196, 204). On January 28, 1997, HGS filed a patent application (U.S. Application No.

60/035,722) disclosing that DR4 contains all of the canonical structural features of a death receptor (an ECD with CRDs, a transmembrane domain and an intracellular death domain) and shares significant homology with the known death receptors TNFR1, Fas and DR3. (Facts 35-36, 190-196, 204). The application also disclosed how to: (i) make DR4 DNA to express a soluble DR4 protein; (ii) use DR4 protein to make agonistic and antagonistic monoclonal antibodies that bind to the ECD of DR4; and (iii) use such antibodies to induce or inhibit apoptosis (e.g., to treat cancer or AIDS). (Facts 42-43, 271-283, 204). Moreover, the patent application contained working examples demonstrating that, like TNFR1, Fas and DR3, overexpression of DR4 triggers apoptosis, which is dependent on the presence of the intracellular death domain. (Facts 37-39, 271-283, 204). The patent application also disclosed that DR4 binds to the ligand TRAIL. (Facts 40-41). The results of these studies were submitted to *Science* on February 6, 1997, accepted for publication on February 28, 1997 and published on April 4, 1997. (Facts 46, 181, 190-196, 204).

Thus, well before Party Ni's March 10, 1997 asserted conception date, Party Ni was not only aware of the extensive scientific literature concerning the prior art death receptors, TNFR1 and Fas, but had themselves already made substantial contributions to the field by identifying and characterizing DR3 (already published) and DR4 (already accepted for publication). (Facts 9-46).

### 3. *By March 10, 1997, Party Ni Had a Corroborated Conception of a TRAIL-R Polypeptide Having an Amino Acid Sequence that Is At Least 90% Identical to the Amino Acid Sequence of Rauch's SEQ ID NO:2 and which binds to TRAIL*

By March 10, 1997, Party Ni identified a fifth death receptor, DR5. By November 1996, Dr. Ni identified a cDNA clone that contained a partial sequence of the ECD of DR5. (Fact 47). At that time, based on the significant homology of this partial sequence to the ECD of other TNF

receptors, Party Ni contemplated that this new sequence encoded a portion of a novel TNF receptor. (Facts 48-58). Dr. Ni has testified that by February 19, 1997, Party Ni identified a full-length DR5 clone and obtained the full-length DR5 DNA sequence. (Facts 48-58).

On February 18, 1997, Dr. Ni sent an e-mail to HGS' Vice President and General Counsel Robert Benson and co-inventors Reiner Gentz and Craig Rosen, notifying them that he had obtained the full-length DNA and amino acid sequences of TR7 (also known as DR5 or TRAIL-R2), and that TR7 (i.e., DR5) is "a new TNFR-like gene which contains a death domain." (Facts 59-63). The subject line of the e-mail indicates that Dr. Ni had renamed the TR7 receptor Death Receptor 5 (DR5). (Fact 59). The DR5 protein sequence included in the e-mail is identical to the extracellular and transmembrane portions of the DR5 protein sequence of Party Ni's SEQ ID NO:2, while containing some sequencing errors in the intracellular domain of the protein. (Fact 64). Drs. Ni, Yu and Gentz have testified that by February 19, 1997, they obtained corrected DR5 DNA and amino acid sequences, which are identical to the DNA and amino acid sequences of Ni's SEQ ID NOs:1 and 2, respectively. (Facts 65-69, 214-224). Party Ni's recognition of the correct full-length DR5 sequence is evidenced by a project report, last modified by Dr. Gentz on February 19, 1997, disclosing the full-length DNA sequence of DR5. (Facts 65-69, 214-224). The DNA sequence obtained on February 19, 1997 encodes an amino acid sequence of DR5 that is the same sequence that is set forth in Ni's priority applications, as well as the involved application, as SEQ ID NO:2 ("Ni's SEQ ID NO:2") (Facts 65-69, 214-224), and is more than 90% identical to Rauch's SEQ ID NO:2. (Facts 65-69, 214-224).

By March 10, 1997, Party Ni recognized that DR5 protein binds to TRAIL. Even before Party Ni had obtained the full-length DR5 DNA and protein sequences, it recognized the substantial sequence homology between DR4 and DR5. (Fact 70). By February 19, 1997, Party

Ni had obtained the full-length DR5 DNA and protein sequences, and on February 20, 1997, Dr. Ni sent an email to Dr. Dixit providing him with the full-length DR5 DNA and protein sequences, and noting good homology between DR5 and DR4 (TRAIL-R1) and TR5 (TRAIL R3). (Fact 71). The email includes an alignment showing 70-80% sequence identity between DR5 and DR4 at the DNA level, and about 55-65% sequence identity at the amino acid level. (Fact 71). On February 21, 1997, Dr. Ni sent an email to Dr. Pan indicating that he had sent the sequence for DR5/TR7 to Dr. Dixit on February 20, 1997 and noting the good homology between DR5/TR7 and other death receptors. (Fact 72). The related testimony of Party Ni's inventors could be further corroborated by Drs. Vishva Dixit and James Pan, if compelled to testify. (Fact 73).

Drs. Ni, Yu and Gentz have testified that by March 10, 1997, they recognized the remarkable identity and homology between DR4 and DR5, especially in the extracellular domain and the intracellular death domain, and further recognized that DR4 and DR5 share the same pattern of conserved cysteine residues in their extracellular domain. (Facts 70, 76). On March 10, 1997, Dr. Ni sent an email to Reinhard Ebner with several attachments, one of which was entitled "One Year Research Plan for TNF Superfamily and Related Proteases." (Facts 75, 80, 82-83, 85). The authors of the research proposal were Party Ni inventors Guo-Liang Yu, Jian Ni and Reiner Gentz. (Facts 75-78, 80). In the research proposal, Drs. Ni, Yu and Gentz recognized that since DR5 (TR7) has "very close homology with DR4 both at the DNA level and protein level, TRAIL may bind TR7." (Facts 75-81, 83) Indeed, the DR5 protein conceived of by Party Ni inherently binds to TRAIL. (Facts 75-81, 83-84).

Moreover, Drs. Ni, Yu and Gentz have testified that by March 10, 1997, they recognized that DR5 was a novel death receptor that induces apoptosis. (Facts 45, 79). Dr. Ni has testified

that upon obtaining the DNA and amino acid sequences of DR5, he recognized the presence of a death domain in DR5 and recognized DR5's substantial homology to TNFR1, Fas, and DR3. (Fact 86). He further recognized that DR5 would induce apoptosis in cells. (Fact 86). As further shown through the testimony of Drs. Yu and Gentz, Party Ni had recognized DR5 would exhibit apoptotic activity. (Fact 79).

Party Ni has asked Dr. Roberto Testi, an expert in the field of death receptors and apoptosis, to evaluate whether it would have been reasonable for Party Ni to have recognized, by March 10, 1997, that DR5 was a novel death receptor that binds TRAIL and induces apoptosis in view of the state of the art and the specific information of which Party Ni was aware by March 10, 1997. (Fact 204). Additionally, Dr. Testi has evaluated whether he, or a person of ordinary skill in the art, would have reached similar conclusions as reached by Party Ni if faced with the same information by March 10, 1997. (Fact 204). According to Dr. Testi, he and others of ordinary skill in the art would have reached similar conclusions faced with such information. (Facts 157-164, 174, 225-255, 261-266, 204).

#### *4. Party Ni's Complete Corroborated Conception of at Least One Utility by March 10, 1997*

Party Ni's complete corroborated conception included at least one practical utility for an embodiment of count 1. Party Ni understood how to make and use DR5 protein in order to make agonistic and antagonistic antibodies that could be used to induce or inhibit apoptosis, e.g., in the treatment of disease such as cancer and AIDS. (Facts 58, 87, 92-93). Party Ni's recognition of at least one practical utility is further demonstrated by a research proposal prepared by Drs. Ni and Gentz, entitled "TNF ligands and Receptors Superfamily Proposal, II. Immunoadhesins, Immunotoxins and Mabs proposal." (Fact 88). The proposal outlined a strategy that included, *inter alia*, making and using modulators of TNF receptors, including soluble TNF receptor-IgG

fusion proteins (e.g., immunoadhesins) and agonistic and antagonistic monoclonal antibodies that bind to each novel death receptor identified by HGS, including DR5. (Fact 89). The proposal also stated that such immunoadhesins and antibodies could be used to mimic or block the function of the receptor, e.g., to treat cancer or AIDS. (Fact 90). The proposal specifically identifies TR7 (DR5), as one of the subjects of the proposal. (Fact 89). On February 17, 1997, Dr. Ni sent this research proposal to co-inventors Reiner Gentz and Craig Rosen. (Fact 88). On March 10, 1997, Dr. Ni sent an email to Reinhard Ebner attaching three proposals, one of which was the February 17, 1997 proposal. (Fact 75).

Party Ni's proposal demonstrates that Party Ni had contemplated making soluble fusion proteins (e.g., immunoadhesins), and to produce DR5 protein in order to make monoclonal agonistic and antagonistic antibodies. Furthermore, methods of making and using such soluble fusion proteins (e.g., immunoadhesins) and to make such antibodies were routine by March 10, 1997. (Facts 176-178).

Moreover, Dr. Testi has testified that, after having obtained the full-length DR5 sequence, it would have been routine to make and use the encoded protein, e.g., to generate agonistic and antagonistic antibodies, and that it would have been reasonable for Party Ni to have recognized that such antibodies could be used to induce or inhibit apoptosis. (Facts 143-150, 284-288, 204). Additionally, Dr. Testi has testified that, after having obtained the full-length DR5 sequence, it would have been routine to make and use soluble DR5 fusion protein such as an immunoadhesin and that it would have been reasonable for Party Ni to have recognized that such a fusion protein could be used to inhibit apoptosis. (Facts 143-150, 267-268, 284-288, 204). Thus, only ordinary skill in the art would have been needed to reduce the invention to practice.

### 5. *Corroboration of Party Ni's Complete Conception and at Least One Utility By March 10, 1997*

The testimony of Party Ni's inventors as to their complete conception by March 10, 1997 is corroborated by the documentary evidence discussed above, which has been authenticated by the testimony of Biegie Lee and Michael Fannon. (Facts 455-479). The testimony of Party Ni is further corroborated by the independent testimony of Robert Benson, who has testified that he understood from the February 18, 1997 email from Dr. Ni containing the full-length DR5 sequence that Party Ni recognized DR5 as a death receptor and that DR5 induces apoptosis. (Facts 59, 94). The testimony of Party Ni is further corroborated by the independent testimony of Reinhard Ebner, who has testified that he understood from the March 10, 1997 email received from Dr. Ni that Party Ni recognized that DR5 is a death receptor and that DR5 binds TRAIL and could be used to make immunoadhesins and to produce DR5 protein in order to generate agonistic and antagonistic antibodies, which could be used to induce or inhibit apoptosis. (Facts 75, 80, 82, 83, 85, 95-98).

### 6. *Party Ni's Complete Corroborated Alternative Conception #2 by March 20, 1997*

As an alternative to the assertion that Ni had a complete corroborated conception by March 10, 1997, Party Ni further asserts that it had a complete corroborated conception by March 20, 1997. Party Ni has testified that by March 20, 1997 they had obtained the full-length DNA and amino acid sequences of DR5 and had repeatedly asserted that DR5 binds to TRAIL, as evidenced by the email communications sent by Dr. Ni on each of March 10, 11, 14 and 20, 1997 with essentially the same attached research plan as was sent to Reinhard Ebner on March 10, 1997, indicating that DR5 (TR7) has "very close homology with DR4 both at the DNA level and protein level, TRAIL may bind TR7." (Facts 99-103). For example, on March 20, 1997, Dr. Ni sent an email to Dr. Dixit with the same attached research plan as was sent to Reinhard Ebner

on March 10, 1997. (Fact 103). Thus, Party Ni had a fully stable and complete corroborated conception by March 20, 1997. The testimony of Party Ni's complete conception by March 20, 1997 is corroborated by the documentary evidence discussed above, which has been authenticated by the testimony of Biegie Lee and Michael Fannon (Facts 455-479), by the independent testimony of Mr. Benson and Dr. Ebner and could be further corroborated by Dr. Vishva Dixit and Dr. James Pan, if compelled to testify in the present interference. (Fact 73).

### *7. Party Ni's Complete Corroborated Alternative Conception #3 by March 25, 1997*

As a further alternative to the asserted March 10 and March 20, 1997 conception dates, Party Ni asserts that it had a complete corroborated conception of the Count by March 25, 1997. By this date, in addition to the above, the inventors had obtained experimental confirmation that DR5 both (i) binds to the ligand TRAIL and (ii) induces apoptosis. (Facts 112-114, 116-119, 121-130, 131-142, 441-442). As discussed below, the confirmatory data were generated in the laboratory of Dr. Vishva Dixit at the University of Michigan by Dr. James Pan while he was working at the request of Party Ni and Dr. Pan's activities accrue to the benefit of Party Ni. *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1230, 32 U.S.P.Q.2d 1915, 1921-22 (Fed. Cir. 1994).

#### *(a) Activities by Drs. Vishva Dixit and James Pan Accrue to the Benefit of Party Ni*

Because of the limited resources available at HGS in the mid-to-late 1990's, HGS entered into a Material Transfer Agreement (MTA) with the University of Michigan in 1994, which was subsequently amended several times. (Fact 104). This MTA identified Dr. Vishva Dixit as the Principal Investigator under the MTA. (Fact 105). As a result of this MTA, Dr. Ni sent to Dr. Dixit cDNA clones encoding DR5, along with the DNA and amino acid sequence of DR5. (Facts 106-107). By that time, Dr. Dixit's laboratory was already equipped to perform the ligand

binding and overexpression studies using well-established, art-known assays and reagents. (Fact 108). Based on Dr. Ni's prior collaborations with Dr. Dixit's laboratory involving death receptors (DR4) and in view of the state of the art, Dr. Ni understood that a member of Dr. Dixit's laboratory (such as Dr. Pan) would confirm the ability of DR5 to induce apoptosis in an overexpression assay system, and confirm that DR5 binds to TRAIL, e.g., in a co-immunoprecipitation assay. (Fact 108). Indeed, Dr. Pan carried out various assays employing the DR5 DNA and protein (Ni's SEQ ID NOs: 1 and 2, respectively) and experimentally confirmed the inventors' expectation that DR5 binds to the ligand TRAIL and induces apoptosis. (Facts 112-114, 116-119, 121-130, 131-142, 441-442).

***(b) Drs. Vishva Dixit and James Pan are Unavailable Witnesses***

Notwithstanding HGS' prior collaboration with Drs. Dixit and Pan, Drs. Dixit and Pan are unavailable witnesses. (Facts 449-450). As discussed in Ni Miscellaneous Motion 6, currently before the Board, Dr. Dixit is now an employee of Genentech (HGS' opponent in Interference No. 105,361) and requires either (i) a subpoena or (ii) to be named an inventor on the involved HGS application before he will provide testimony in the present interference. (Fact 451). The latter requirement simply is not reasonable. Likewise, Dr. Pan also has made unreasonable demands in exchange for his testimony and has not yet agreed to testify under reasonable terms and conditions. (Fact 452). The unavailable declarant exception to the hearsay rule identifies five examples of unavailability, one of which is the inability to procure testimony of a declarant by process of other reasonable means. FRE 804(a)(5). Likewise, in civil cases, inability to procure the declarant's attendance by reasonable means is equivalent to inability to serve a subpoena. 5-804 Weinstein's Federal Evidence § 804.03(6)(a)(citing *Trade Dev. Bank v. Continental Ins. Co.*, 469 F.2d 35 (2d Cir. 1972); *Perricone v. Kansas City S. Ry. Co.*, 630 F.2d 317 (5th Circuit 1980); *McIntyre v. Reynolds Metal Co.*, 468 F.2d 1092 (5th Circuit 1973);

*United States v. Squella-Avendano*, 478 F.2d 433 (5th Circuit 1973)). Despite Party Ni's exhaustive attempts to secure the testimony of Dr. Pan by using more than reasonable means, Party Ni has been unable to procure his testimony. (Fact 452). Similarly, despite Party Ni's exhaustive attempts to secure the testimony of Dr. Dixit by using more than reasonable means, Party Ni has been unable to procure the testimony of Dr. Dixit. (Fact 451).

Likewise, Party Ni has been unsuccessful in obtaining Dr. Pan's original laboratory notebooks from the former employer of Drs. Pan and Dixit, the University of Michigan. (Fact 453). Dr. Pan's laboratory notebooks should also be admissible as records of regularly conducted activity under FRE 803(6). In the absence of Dr. Pan's testimony as to the content of his laboratory notebooks and the experiments he conducted and/or supervised relating to DR5, Party Ni has asked Dr. Reinhard Ebner to review, and explain how he or other persons of ordinary skill in the art would interpret, the contents of Dr. Pan's laboratory notebooks. (Fact 454).

The situation in the present interference is a case of first impression and is thus unlike the evidentiary pitfalls that trapped the parties in *Stampa* and *Chen*. *Stampa v. Jackson*, 77 U.S.P.Q.2d 1105, 1120, (BAPI 2005); *Chen v. Bouchard*, 2002 Pat. App. LEXIS 201 (BPAI August 2, 2002). Unlike *Stampa*, Party Ni has promptly made the Board fully aware that Drs. Dixit and Pan are unavailable witnesses and of Party Ni's efforts to secure the testimony of Drs. Dixit and Pan. Furthermore, Party Ni has fully complied with 37 C.F.R. § 41.158(b), notwithstanding the fact that Dr. Ebner, rather than Dr. Pan, has testified to satisfy the requirements of the rule. (Facts 448, 454).

*(c) By March 25, 1997, Dr. Pan Experimentally Confirmed Party Ni's Expectation That DR5 Both Binds TRAIL and Induces Apoptosis*

Dr. Ni communicated to Dr. Pan his expectation that DR5 would bind to TRAIL, which was based on Ni's observation of the significant sequence homology and the shared cysteine residues in the ECD between DR5 and the TRAIL receptor known as DR4. (Fact 109). In addition, Dr. Ni communicated to Dr. Pan that, based on the significant homology between DR5 and other death receptors (DR4, DR3, Fas and TNFR1) as well as the structure of the cysteine-rich domains in the extracellular domain, Party Ni expected that DR5 induces apoptosis. (Facts 110-111). According to Dr. Pan's laboratory notebooks as explained by Dr. Ebner, Dr. Pan used the full-length DR5 DNA to create a fusion protein that includes the Fc region of an immunoglobin fused to the ECD of DR5 ("Fc-ECD DR5 fusion protein"), which he used to confirm that DR5 binds to the ligand TRAIL as Party Ni had expected. (Facts 112-114). Dr. Pan had performed similar assays using DR3 and DR4 in accordance with the MTA and collaboration between HGS and Michigan. (Facts 108, 115). By March 25, 1997, according to his laboratory notebooks explained by Dr. Ebner, Dr. Pan confirmed experimentally that DR5 binds to TRAIL. (Facts 112-114, 116-119). Dr. Ebner has testified that it is reasonable for a person of ordinary skill in the art to conclude that, by March 25, 1997, the results with the Fc-ECD DR5 fusion protein demonstrate that the full-length DR5 protein binds TRAIL. (Fact 120).

By March 11, 1997, according to Dr. Pan's laboratory notebooks explained by Dr. Ebner, Dr. Pan began performing apoptosis assays in which a full-length DR5 gene was overexpressed in cells to confirm that DR5 induced apoptosis, as the HGS inventors had expected. (Facts 121-130). By March 25, 1997, as evidenced by his laboratory notebooks which have been explained by Dr. Ebner, Dr. Pan confirmed experimentally that DR5 induces apoptosis. (Facts 121-130, 131-142). As a control, Dr. Pan confirmed that DR5 induces apoptosis only when the death

domain is present. (Fact 141). Dr. Pan regularly reported the results of his overexpression and ligand binding experiments to Dr. Ni by both phone and email, and Dr. Pan reported these results to Dr. Ni by March 25, 1997. (Facts 441-442). Furthermore, on March 26, 1997, Dr. Ni sent an email to Dr. Ebner stating that TR7 binds to TRAIL. (Fact 482). Dr. Testi has testified that overexpression assays and ligand binding assays such as those performed by Dr. Pan were routine assays as of March 25, 1997 to confirm the function and native ligand of a death receptor. (Facts 143-268). Moreover, Dr. Testi has testified that it would have been reasonable for Party Ni to have recognized that a full-length DR5 protein binds the ligand TRAIL based on the results of such a ligand binding assay. (Facts 145-266).

The testimony of Party Ni's inventors regarding their complete conception by March 25, 1997 is corroborated by the documentary evidence discussed above, which has been authenticated by the testimony of Biegie Lee and Michael Fannon (Facts 455-479); the independent testimony of Mr. Benson and Dr. Ebner; and the independent testimony of Brad Lorimier, who has testified that upon receiving a March 25, 1997 email from Dr. Ni, he understood that Party Ni had obtained experimental confirmation that DR5 is a death receptor and binds to TRAIL. (Facts 444-445).

### *8. Summary of Complete and Corroborated Prior Conception of Each Element of Count 1*

The facts discussed above demonstrate that Party Ni had a complete and corroborated conception of each element of Count 1 by March 10, 1997 or, alternatively, by March 20 or 25, 1997. By March 10, 1997, Party Ni's conception was stable, and the amino acid sequence that Party Ni identified as Ni's SEQ ID NO:2 is at least 90% identical to Rauch SEQ ID NO:2, as required by Count 1. (Facts 7-8, 198-203, 208-213). Moreover, the inventors knew how to make and use DR5 protein, e.g., to make Fc fusion proteins (e.g., immunoadhesins) and in order

to make agonistic and antagonistic antibodies to DR5 that could be used induce or inhibit apoptosis, e.g., to treat cancer (agonists) or AIDS (antagonists). (Facts 87-98). Only ordinary skill in the art would have been needed to reduce the invention to practice.

Alternatively, Party Ni conceived of the subject matter of Count 1 by March 20, 1997 by which time the inventors had repeatedly asserted that DR5 binds TRAIL. (Facts 99-103). In the alternative, Party Ni conceived of the subject matter of Count 1 by March 25, 1997, by which time the inventors had obtained experimental confirmation that DR5 was capable of inducing apoptosis and binding to the apoptosis-inducing ligand TRAIL. (Facts 112-114, 116-119, 121-130, 131-142, 441-442).

***B. Party Ni Had a Corroborated Actual Reduction to Practice by March 25, 1997***

Actual reduction to practice occurs when the inventor (a) made an embodiment or performed a process that meets every element of the interference count, and (b) demonstrated that the embodiment is capable of operating for its intended purpose. *Eaton v. Evans*, 204 F.3d 1094, 1097-98, 53 U.S.P.Q.2d 1696, 1698-99 (Fed. Cir. 2000). However, in demonstrating that an embodiment is capable of operating for its intended purpose, "the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use." *Scott v. Finney*, 34 F.3d 1058, 1063, 32 U.S.P.Q.2d 1115, 1119 (Fed. Cir. 1994). When the problem to be solved "does not present myriad variables, common sense similarly permits little or no testing to show the soundness of the principles of operation of the invention." *Scott*, 34 F.3d at 1063, 32 U.S.P.Q.2d at 1119.

It is not necessary for the inventor to personally reduce his invention to practice; "activities by others working explicitly or implicitly at the inventor's request will inure to his benefit." *Cooper v. Goldfarb*, 154 F.3d 1321, 1332, 47 U.S.P.Q.2d 1898, 1905 (Fed. Cir. 1998) (quoting 3 Donald S. Chisum, Chisum on Patents § 10.06[3] (1995)); *Burroughs Wellcome Co.*

*v. Barr Lab., Inc.*, 40 F.3d 1223, 1230, 32 U.S.P.Q.2d 1915, 1921-22 (Fed. Cir. 1994) (testing of AZT by scientists at the National Institutes of Health inures to the benefit of the pharmaceutical manufacturer that conceived of the invention); *Gianladis v. Kass*, 324 F.2d 322, 328, 139 U.S.P.Q. 300, 305 (CCPA 1963) (attorney's efforts inure to the benefit of the inventor in establishing diligence). As explained below, Dr. Pan's work constituted an actual reduction to practice and inures to the benefit of Party Ni.

As explained in § IV.A, *supra*, Party Ni had a complete and permanent idea by March 10, 1997 that DR5 binds to the ligand TRAIL and induces apoptosis. As evidenced by Dr. Pan's laboratory notebooks which have been explained by Dr. Ebner, Dr. Pan used a full-length DR5 DNA to make an Fc-ECD DR5 fusion protein which he used in a ligand binding assay. (Facts 112-114). Using such an assay, Dr. Pan confirmed that DR5 binds to TRAIL. (Facts 112-114, 116-119). Furthermore, as evidenced by his laboratory notebooks which have been explained by Dr. Ebner, Dr. Pan confirmed that overexpression of the full-length DR5 protein in mammalian cells induces apoptosis. (Facts 121-130, 131-142).

Dr. Testi has testified that such ligand binding assays and overexpression assays to confirm the native ligand and function of a death receptor were routine assays as of March 10, 1997. (Facts 261,267,278). Moreover, Dr. Testi has testified that it would have been reasonable for Party Ni to have recognized, based on results of a ligand binding assay using the Fc-ECD DR5 fusion protein, that the full-length DR5 protein binds the ligand TRAIL and the use of such a soluble receptor was a standard method in the art for assessing ligand binding. (Facts 145-266). Thus, the demonstration that an Fc-ECD DR5 fusion protein binds to TRAIL satisfies the testing requirements, as set forth in *Scott v. Finney*, to show that an embodiment of DR5 that meets every limitation of the count works for its intended purpose, to bind TRAIL.

When testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur. *Estee Lauder Inc.v. L'Oreal, S.A.*, 129 F.3d 588, 594-95, 44 USPQ2d 1610, 1614-15 (Fed. Cir. 1997). As evidenced by Dr. Pan's laboratory notebooks which have been explained by Dr. Ebner, by Party Ni's March 25, 1997 asserted actual reduction to practice date, Dr. Pan had completed the experiments in which he demonstrated that (i) a Fc-ECD DR5 fusion protein binds the ligand TRAIL and (ii) the full-length DR5 induces apoptosis. (Facts 112-114, 116-119, 121-130, 131-142). Moreover, Party Ni appreciated these results by March 25, 1997, on which date Dr. Ni sent an email to Bradley Lorimier and others stating "[w]e have obtained the data which indicates that TR5 and TR7 [DR5] are additional receptors for TRAIL." (Facts 442-446). Thus, Party Ni had full appreciation of a successful reduction to practice by March 25, 1997.

Because Dr. Pan's testing was explicitly or implicitly at Party Ni's request and confirmed that DR5 binds the ligand TRAIL and induces apoptosis, it showed that Party Ni had an earlier definite and permanent idea of the invention. See *Burroughs Wellcome*, 40 F.2d at 1230 ("because the testing confirmed the operability of the inventions, it showed that the Burroughs Wellcome inventors had a definite and permanent idea of the inventions"). In *Cooper v. Goldfarb II*, the court determined whether Cooper, who conceived of the invention, could obtain the benefit of collaborator Goldfarb's knowledge of fibril lengths of the material Goldfarb tested. *Cooper v. Goldfarb*, 240 F.3d 1378, 1385, 57 U.S.P.Q.2D (BNA) 1990, 1994 (Fed. Cir. 2001). The court applied the following test in determining whether a party's activities towards an actual reduction to practice inure to the benefit of another:

> (1) whether Cooper had conceived the fibril length limitation of the interference count, (2) whether Cooper had an expectation that the ePTFE material that he furnished to Goldfarb had the required fibril lengths, and (3) whether Cooper submitted the material to

> Goldfarb for testing to determine whether it had the required fibril lengths.

*Cooper v. Goldfarb*, 240 F.3d at 1385, 57 U.S.P.Q.2D at 1994. Applying the *Cooper* test in the present interference shows that, Party Ni: (1) had conceived the TRAIL binding limitation of the count; (2) had the expectation that the full-length DR5 DNA provided to Dr. Pan would be used to make the full-length DR5 protein that would bind to TRAIL; and (3) had submitted the full-length DR5 DNA to make the full-length DR5 protein for testing to determine if DR5 binds TRAIL. Thus, under *Burroughs* and *Cooper*, Dr. Pan's activities inure to the benefit of Party Ni.

Party Ni has established by more than a preponderance of the evidence and clear and convincing evidence and certainly proven it under the if unrebutted standard that is now applicable that the inventors had an actual reduction to practice by March 25, 1997.

### *C. Party Ni Did Not Abandon, Suppress or Conceal Its Invention*

Party Ni did not abandon, suppress or conceal its invention between March 25, 1997, the date of its actual reduction to practice, and July 29, 1997, the date of its constructive reduction to practice by filing of U.S. Application No. 60/054,021 ("the '021 application"). The amount of time between reduction to practice and filing is not dispositive, either way, with respect to the issue of suppression or concealment. See, e.g., *Correge v. Murphy*, 705 F.2d 1326, 1330, 217 U.S.P.Q. 753, 757 (Fed. Cir. 1983). In assessing whether an inference of suppression or concealment is appropriate, the totality of the circumstances surrounding the inventor's conduct between actual reduction to practice and filing must be considered. *Fujikawa*, 93 F.3d at 1568, 39 U.S.P.Q.2d at 1902-03. During this time period, Party Ni and those working on its behalf engaged in significant steps toward perfecting the invention and preparing the '021 application. (Facts 290-437). From March 25, 1997 until June 4, 1997, as evidenced by Dr. Pan's laboratory notebooks which have been explained by Dr. Ebner, Dr. Pan continued the overexpression and

ligand binding experiments with the full-length DR5 and the Fc-ECD DR5 fusion protein. (Facts 290-425). Furthermore, between June 4, 1997 and July 29, 1997, HGS attorneys prepared a patent application directed to DR5, clearly evincing the lack of abandonment, suppression and concealment. (Facts 426-437). Likewise, Dr. Ni and others sought to publish a scientific paper relating to DR5. (Fact 426). Thus, Party Ni did not abandon, suppress or conceal its invention.

### *D. Alternatively, Party Ni Asserts That It Was Diligent in Working Towards a Reduction to Practice*

In the event that the Board determines that Party Ni cannot or may not prove a corroborated actual reduction to practice by March 25, 1997, Party Ni asserts that it worked with reasonable diligence toward reducing to practice the subject matter of Count 1 from just before Party Rauch's awarded constructive reduction to practice, on March 28, 1997, until Party Ni's constructive reduction to practice on July 29, 1997. In the Decision - Motions - Bd.R. 125(a) Paper 101 ("Decision on Motions") for the present interference, issued on March 26, 2007, the Board recognized that U.S. Application No. 60/054,021, filed on July 29, 1997, described an enabled embodiment within the scope of Count 1 and accorded Party Ni benefit to the '021 application for the purpose of priority. (Fact 447).

One who is last to reduce to practice but first to conceive may establish priority by showing reasonable diligence extending from a time prior to the other party's conception to its own reduction to practice. 35 U.S.C. § 102(g) (2004); *In re Jolley*, 308 F.3d 1317, 1326, 64 U.S.P.Q.2d 1901, 1908 (Fed. Cir. 2002). Reasonable diligence does not require that a party work constantly on the invention to the exclusion of all other work. *Mycogen Plant Science, Inc. v. Monsanto Co.*, 252 F.3d 1306, 1316, 58 U.S.P.Q.2d 1891, 1899 (Fed. Cir. 2001). To establish diligence, a party must provide specific details regarding dates and activities that took place

during the critical period. *Kendall v. Searles*, 173 F.2d 986, 993, 81 U.S.P.Q.363, 369 (CCPA 1949).

As described in more detail below and set forth on the accompanying day-to-day calendar of activities (Appendix D) and the timeline (Appendix C), the activities that accrue to Party Ni's benefit with respect to diligence toward reduction to practice include:

- The work of external collaborator Dr. James Pan in confirming the TRAIL-binding and apoptosis-inducing activity of DR5 (Facts 290-425);
- The work of co-inventor Guo-Liang Yu in examining the distribution of DR5 expression in normal and disease tissues (Fact 438); and
- The work of HGS attorney Andy Brookes and outside Patent Agent Karen Markowicz to prepare and file a patent application on July 29, 1997, which can be tacked onto the end of diligent efforts towards an actual reduction to practice. (Facts 426-437).

### *1. Dr. Pan's Activities Employing DR5 DNA and Protein Accrue to the Benefit of Party Ni*

According to Dr. Pan's laboratory notebooks as explained by Dr. Ebner, between the time period of March 25, 1997 and June 4, 1997, Dr. James Pan continued to perform ligand binding studies using the ECD of DR5 to confirm his initial results that DR5 specifically binds the ligand TRAIL. (Facts 290-296, 379-425). In addition, during this time period, Dr. Pan diligently repeated the experiments to confirm the initial results that DR5 induces apoptosis when overexpressed. (Facts 297-316). Between March 25, 1997 and June 4, 1997, as explained through Dr. Ebner's review of Dr. Pan's laboratory notebooks, Dr. Pan transfected the full-length DR5 into different mammalian cell lines for overexpression assays to confirm that DR5 induces apoptosis. (Facts 297-316). Furthermore, as evidenced by Dr. Pan's laboratory notebooks which

have been explained by Dr. Ebner, Dr. Pan also characterized the apoptosis signalling pathway using caspase inhibitors. (Facts 317-378, 384-425). Additionally, as evidenced by Dr. Pan's laboratory notebooks which have been explained by Dr. Ebner, Dr. Pan performed competition assays with the Fc ECD DR5 fusion protein to confirm that the soluble extracellular domain of DR5 binds to TRAIL and therefore inhibits TRAIL-induced apoptosis. (Facts 379-425). As evidenced by Dr. Pan's laboratory notebooks which have been explained by Dr. Ebner, Dr. Pan's work on DR5 was virtually continuous during the period of March 25, 1997 through June 4, 1997 except between the period of April 16 to 22, 1997, when Dr. Pan did not record any activities. (Facts 290-425). The fact that Dr. Pan did not record activities in any of his laboratory notebooks during that period suggests that Dr. Pan was temporarily away from the laboratory (e.g., on vacation or at a scientific conference) and that inactivity is excusable. Dr. Pan could provide testimony on this point if he were compelled to testify. (Fact 73). Dr. Pan's activities are detailed in Facts 290-425, and on the day-to-day calendar of activities, Appendix D. For at least the reasons discussed above, these activities performed by Dr. James Pan accrue to the benefit of Party Ni.

### *2. Attorney Diligence Accrues to the Benefit of Party Ni*

Efforts spent in preparing a patent application can be used to establish the diligence of an inventor in seeking to constructively reduce an invention to practice. *Gianladis*, 324 F.2d at 328, 139 U.S.P.Q. at 305. Diligence may be established by "tacking" prior activity toward an actual reduction to practice (e.g., experimentation or testing a working embodiment) onto later activity toward constructive reduction to practice (e.g., the preparation and filing of a patent application). *Rey-Bellet v. Englehardt*, 493 F.2d 1380, 1387-88, 181 U.S.P.Q. 453, 458 (CCPA 1974). Beginning by June 4, 1997 and continuing until July 29, 1997, the HGS inventors, together with their attorneys, worked diligently toward preparing a patent application that describes and

enables an embodiment of count 1. (Facts 426-437). These activities are detailed on the accompanying day-to-day calendar of activities, Appendix D.

On June 4, 1997, Jian Ni sent an email to several HGS employees, including DR5 co-inventors Drs. Yu, Gentz and Rosen and patent attorneys Robert Benson and Andy Brookes, providing an electronic copy of a completed DR5 *Science* manuscript. (Facts 426-427). Dr. Ni has testified that the manuscript was provided to patent attorneys Robert Benson and Andy Brookes to consider whether the subject matter disclosed therein should be incorporated into a patent application. (Facts 426, 428-429). A hard copy of the manuscript, with an approval coversheet, was circulated to Robert Benson and others on June 5, 1997. (Fact 430). This activity is corroborated by the independent testimony of Robert Benson, who has testified he understood that he and Andy Brookes were to review the manuscript and determine whether a patent application should be prepared. (Facts 429-437).

By June 19, 1997, the filing of a new provisional application directed to DR5 had been authorized by Craig Rosen, pending review of the DR5 Science manuscript by the Intellectual Property department. (Fact 431). In assessing attorney diligence toward a constructive reduction to practice, it is not necessary for the attorney to focus exclusively on the application at issue, when there is a backlog of work; it is sufficient that the applications be taken up in a chronological and expeditious manner. *Rines v. Morgan*, 250 F.2d 365, 369, 116 U.S.P.Q. 145, 148 (CCPA 1957); Bey, 806 F.2d at 1029, 231 U.S.P.Q. at 970. Between June 19, 1997 and July 15, 1997, HGS patent attorney Andy Brookes reviewed "a stack" of manuscripts, including the DR5 Science manuscript, to determine whether updated patent applications should be prepared. (Fact 432). On July 15, 1997, Andy Brookes notified administrative assistant Kathryn Beckman

that he had finished reviewing the "stack of manuscripts," and that the DR5 manuscript should be included as part of a CIP (continuation-in-part). (Fact 433).

Between June 19, 1997 and July 29, 1997, the HGS legal department was short-staffed and had numerous other patent applications to file first. (Facts 432-433). As evidence of the workload burden during this period, Robert Benson has testified that Andy Brookes reviewed and filed over 70 patent applications between June 1 and July 29, 1997. (Facts 432-433). Thus, HGS acquired the help of patent agent Karen Markowicz to draft the second provisional application on DR5. (Fact 434, 480). Andy Brookes provided Karen Markowicz with the information provided by Party Ni to draft the application. (Fact 435, 480-481). Karen Markowicz submitted several drafts of the patent application to the inventors and Andy Brookes for review. (Fact 428). On July 29, 1997, HGS patent attorney Andy Brookes filed the patent application as Application No. 60/054,021. (Facts 436-437). These activities are listed in detail in Facts 426-437 and in Appendix D.

### 3. *Summary of Acts of Diligence*

As discussed above, and as is clear from the accompanying day-to-day calendar of events (Appendix D), Party Ni exercised reasonable diligence in working to reduce the invention to practice. Such diligence occurred from just prior to Party Rauch's entry into the field until Party Ni's constructive reduction to practice on July 29, 1997. As shown in Appendix D, various days of inactivity are excused for the indicated reasons.

Party Ni has accounted for the entire critical period by showing affirmative acts toward a reduction to practice, by providing evidence of ongoing experiments or attorney diligence, or by providing an excuse or reason for the inactivity. See Appendix D, *Hull*, 90 F.2d at 105, 33 U.S.P.Q. at 508, *Monsanto,* 261 F.3d at 1370, 59 U.S.P.Q.2d at 1939. Additionally, the testimony of the inventors regarding their activities has been corroborated by, *inter alia*, the

testimony of Dr. Reinhard Ebner and Robert Benson, and by various documents provided as Exhibits hereto, as described herein.

### *E. Conclusion--Party Ni has Established Compelling Reasons for Entering the Priority Phase in This Interference*

Party Ni established by more than a preponderance of the evidence that Party Ni was first to have conceived of the subject matter of count 1, and that the inventors had an actual reduction to practice on March 25, 1997 or in the alternative worked with reasonable diligence to reduce the invention to practice from a time just before Party Rauch's awarded constructive reduction to practice of March 28, 1997 until Party Ni constructively reduced the invention to practice on July 29, 1997. Party Ni hereby requests that it be allowed to continue to the priority phase of this interference.

## *V. Discovery is Needed to Help Prove Party Ni's Earliest Corroborated Actual Reduction to Practice and/or Corroborated Conception Coupled with Diligence*

37 C.F.R. § 41.202(e)(2) provides that when testimony or production necessary to show priority is not available without authorization, a party may request discovery in their showing of priority. Therefore, pursuant to 37 C.F.R. § 41.202(e)(2)(i), Party Ni seeks discovery relating to research regarding DR5 that Dr. Pan and/or Dr. Dixit conducted and/or supervised at the University of Michigan ("Michigan"), between November 1, 1996 through July 29, 1997, in accordance with a research collaboration entered into between HGS and Michigan. Discovery is requested for this time period because it will aid Party Ni to show diligence just before Party Rauch's entry into the field until Party Ni's constructive reduction to practice on July 29, 1997. Party Ni's Motion 6, requesting such discovery, is currently pending in the present interference. Granting the requested discovery will allow Party Ni to better comply with the Federal Rules of Evidence and 37 C.F.R. § 41.158(b). In co-pending interference No. 105,380, Party Rauch

likewise requested access to documents relating to Dr. Pan's research activities, specifically Dr. Pan's original laboratory notebooks and testimony regarding the notebooks. (Fact 509).

Party Ni requests discovery from Dr. Pan, Michigan, and Dr. Dixit to help prove its earliest corroborated actual reduction to practice or corroborated conception coupled with diligence. Because Drs. Pan and Dixit conducted and/or supervised research on DR5 at the request of HGS, their testimony relating to this research and any documents in their possession and/or under their control relating to that research is expected to provide corroborated evidence of Party Ni's actual reduction to practice and conception coupled with diligence in reducing the invention to practice. (Facts 484-499). Additionally, Drs. Pan and Dixit carried out their research relating to DR5 at the University of Michigan, and any relevant documents (*e.g.*, laboratory notebooks, emails) in Michigan's possession and/or under their control relating to that research is expected to provide additional evidence of Party Ni's actual reduction to practice or conception coupled with diligence in reducing the invention to practice.

### *A. Party Ni Requests Discovery from Dr. Pan to Prove its Earliest Corroborated Actual Reduction to Practice and/or Corroborated Conception Coupled with Diligence by the Person Having First Hand Knowledge*

Pursuant to 37 C.F.R. § 41.202(e)(2)(i), Party Ni seeks discovery from Dr. Pan relating to his research activities relating to DR5 between November 1, 1996 through July 29, 1997. Dr. Pan's testimony will provide corroborated evidence of Party Ni's actual reduction to practice on March 25, 1997 and corroborated conception coupled with diligence. (see Appendix D). Specifically, Party Ni requests Dr. Pan's original laboratory notebooks containing all gels and inserted materials, as well as Dr. Pan's testimony to explain his laboratory notebooks and research activities relating to DR5. (see 37 C.F.R. § 41.158(b)). Dr. Pan's former counsel provided HGS with photocopies of what were represented to be Dr. Pan's laboratory notebooks; however, HGS has not had access to Dr. Pan's original laboratory notebooks. Likewise, Party

Rauch has requested access to such original laboratory notebooks, including missing gels and other inserted papers presumably kept in the original notebook. (Facts 500,509). As explained above, Dr. Reinhard Ebner has reviewed and explained the contents of Dr. Pan's laboratory notebooks. As described in more detail below, it is believed that Dr. Pan would provide substantially identical testimony as to the contents of his laboratory notebooks, and his research activities relating to DR5 as the testimony offered by Dr. Ebner. (37 C.F.R. § 41.202(e)(2)(ii)). However, obtaining the testimony directly from Dr. Pan would obviate certain evidentiary objections likely to be raised by Party Rauch.

On information and belief, it is expected that Dr. Pan, if compelled to testify, would explain his activities related to DR5 were at the behest of HGS, and took place during the period from about March 11, 1997 through about June 4, 1997. (Fact 501). Specifically, it is believed that Dr. Pan will explain that he used a DR5 nucleic acid, obtained from HGS, to prepare DR5 expression constructs for use in: (1) ligand binding assays to confirm the ability of DR5 to bind to TRAIL; and (2) assays to confirm the ability of DR5 to induce apoptosis. (Facts 502-504). Specifically:

- It is believed that Dr. Pan will testify that by March 25, 1997 he confirmed that DR5 induces apoptosis. (Fact 505).

- It is believed that Dr. Pan will testify that by March 25, 1997 he confirmed that DR5 binds to TRAIL. (Facts 506-507).

Party Ni's expectation as to the substance of Dr. Pan's testimony is based, *inter alia*, on (1) Dr. Pan's notebooks, which have been explained by Dr. Ebner; (2) testimony of Party Ni's declarants, particularly the testimony of Dr. Jian Ni; (3) the nature of the research collaboration between HGS and Michigan, as evidenced by the Material Transfer Agreement; and (4) the

August 1997 manuscript published in the journal *Science* (submitted June 10, 1997) on which Drs. Pan and Dixit are co-authors and which reports (i) such ligand binding assays, and (ii) such apoptosis assays.

Dr. Pan's research activities are important to Party Ni's ability to prove an actual reduction to practice and/or conception coupled with diligence. Dr. Pan can provide first hand knowledge of his activities and of the contents of his laboratory notebooks. It is also important, however, that Dr. Pan explain any gaps in his research activity (e.g., illness?, family emergency?, travel abroad?, etc.). Therefore, Dr. Pan is well suited to corroborate Party Ni's conception and prove an actual reduction to practice and/or conception coupled with diligence, which will inure to the benefit of Party Ni.

In the absence of Dr. Pan's testimony, the Board might (but should not) draw an adverse inference against Party Ni for failing to provide testimony from the person who can best explain his own experimental evidence. *Stampa v. Jackson*, 77 U.S.P.Q.2d at 1120; *Chen v. Bouchard*, 2002 Pat. App. LEXIS 201. Such a result would be highly prejudicial to Party Ni and, therefore, it is in the interest of justice to compel Dr. Pan to provide the above-described testimony and documents.

### *B. Party Ni Requests Discovery from Michigan to Prove An Actual Reduction to Practice and/or Corroborated Conception Coupled with Diligence*

Pursuant to 37 C.F.R. § 41.202(e)(2)(i), Party Ni also requests production of documents in the possession of, or under the control of, Michigan relating to the research conducted in Dr. Dixit's laboratory on DR5, including laboratory notebooks, reports, and communications regarding the research. Party Ni requests production of Dr. Pan's original laboratory notebooks, or at a minimum, access to his original laboratory notebooks, at least some of which are believed to be in the possession, or under the control, of Michigan and/or Dr. Pan. Likewise, Party Rauch

has requested access to such original laboratory notebooks, including all missing gels and other inserted papers kept in the original notebook. (Facts 500,509). Party Ni requests the original notebooks because the photocopied laboratory notebooks provided to HGS do not appear to contain copies of all of the original data believed to have been produced, for example gels containing immunoprecipitation results relating to DR5. As such, the requested discovery will allow Party Ni to better comply with the Federal Rules of Evidence, *e.g.* FRE 901, 1002 and 1003 and with 37 C.F.R. § 41.158.

Party Ni also requests production of communications that relate to DR5 between Drs. Dixit and Pan and HGS from the limited time period of November 1, 1996 through July 29, 1997. It is believed that Michigan has in its possession over 4500 electronic files, including emails, that relate to Dr. Pan and Dr. Dixit's research activities, including communications relating to DR5. (Fact 508). Party Ni requests this information because it is expected to help prove an actual reduction to practice and/or conception coupled with diligence. Given the importance of these documents, it is in the interest of justice to compel Michigan to produce the above-described documents.

### *C. Party Ni Needs the Requested Discovery from Dr. Dixit to Prove an Actual Reduction to Practice and/or Conception Coupled with Diligence*

Pursuant to 37 C.F.R. § 41.202(e)(2)(i), Party Ni also requests testimony and production of documents in the possession of, or under the control of, Dr. Dixit relating to research conducted in his laboratory at Michigan on DR5, from November 1, 1996 through July 29, 1997, including laboratory notebooks, reports, and communications regarding the research.

Party Ni requests testimony and production of documents from Dr. Dixit for the limited time period of November 1, 1996 through July 29, 1997 that relate to DR5. It is believed that Dr. Dixit will provide testimony that will corroborate Party Ni's actual reduction to practice and

conception coupled with diligence. Dr. Dixit acknowledged the Material Transfer Agreement between HGS and Michigan. (Facts 510-512). Therefore, Dr. Dixit was involved in the research activities relating to DR5. Moreover, Dr. Dixit was a conduit of information between HGS and Dr. Pan. The importance of Dr. Dixit's role in the HGS/Michigan collaboration on DR5 is evident by the communications and testimony relating to DR5. (Facts 71,72,102-109,111,181,446,483-499). It is believed that Dr. Dixit will provide further testimony relating to Dr. Pan's activities or the activities of anyone else in his laboratory who was involved in the DR5 research. Given the importance of the research activities conducted in the laboratory of Dr. Dixit, it is in the interest of justice to compel Dr. Dixit to produce the above-described testimony and documents.

## *VI. Conclusion*

As discussed above, Party Ni respectfully disagrees with the Board's conclusion that there does not appear to be a reason to continue this interference. Party Ni has not waived its right to enter the priority phase and has proffered sufficient evidence to merit full consideration on the issue of priority. In fact, Party Ni will prevail on priority because Party Ni had an actual reduction to practice of an embodiment of Count 1 before Party Rauch's awarded benefit date. Alternatively, Party Ni can demonstrate that it had a prior conception coupled with diligence. To aid in its proof of priority, Party Ni requests discovery from Drs. Pan and Dixit and the University of Michigan pursuant to 37 C.F.R. §41.202(e)(2)(i).

## *VII. Request for Oral Hearing*

Party Ni requests an oral hearing prior to entry of any judgment in the present interference.

Date: June 15, 2007
Sterne, Kessler, Goldstein & Fox P.L.L.C.
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Respectfully submitted,

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# EXHIBIT 15

Paper No. 110
ST
12-13-07

Filed on behalf of: Senior Party Adams

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UNITED STATES PATENT AND TRADEMARK OFFICE



BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Richard E. Schafer)

Human Genome Sciences, Inc.
Junior Party
(Patent 6,872,568;
Inventors: Jian Ni, Reiner L. Gentz, Guo-Liang Yu, Craig A. Rosen),

v.

Genentech, Inc.
Senior Party
(Application 10/423,448;
Inventors: Camellia W. Adams, Avi J. Ashkenazi, Anan Chuntharapai, Kyung Jin Kim).

Patent Interference No. 105,361 (RES)

**ADAMS REQUEST FOR RECONSIDERATION**
(of Decision on Motions and/or Order Setting Priority Times)

## ADAMS REQUEST FOR RECONSIDERATION

### I. PRECISE RELIEF REQUESTED

Pursuant to Standing Order ¶ 125, senior party Adams ("Adams") requests reconsideration of the Decision on Motions (Paper No. 107) and the Order- Priority Times – Bd.R. 104(c) (Paper No. 109; "the Priority Order"), to the extent these papers advance this Interference to a priority contest. For the reasons discussed below, Adams respectfully submits that judgment should be entered against junior party Ni ("Ni") with respect to Count 1 and Count 2 or, in the alternative, Ni should be placed under an Order to Show Cause why judgment on priority should not be entered against it.

### II. THE EVIDENCE

A list of exhibits or papers that Adams believed was overlooked or misapprehended by the Board is set forth in Appendix A.

### III. STATEMENT OF FACTS RELIED UPON IN REQUEST FOR RECONSIDERATION

A statement of material facts relied upon in support of this request for reconsideration is set forth in Appendix B.

### IV. REASONS WHY RELIEF REQUESTED SHOULD BE GRANTED

#### A. The Decision on Motions and the Priority Order

In the Decision on Motions, the Board denied Ni Substantive Motion 3 and held that Ni was not entitled to the benefit of any earlier-filed applications with respect to Count 1 or Count 2. *See*, Facts 9-12. On page 2, lines 11-18, of the Priority Order, Time Period 11 specifies that Ni must file its priority motion and serve (but not file) its priority evidence. *See*, Facts 13-15. Collectively, these papers appear to reflect the Board's conclusion that Ni's Priority Statement sets forth a ground upon which Ni could establish priority of invention with respect to Count 1

and Count 2. For the reasons set forth herein, it is believed that the Board has overlooked or misapprehended facts relating to Ni's Priority Statement and Ni's burden of proving priority in view of the Decision on Motions. Accordingly, reconsideration is respectfully requested.

### B. Board Rules Governing Benefit, Constructive Reductions to Practice, and Priority Statements

Bd.R. 201 provides that "*accord benefit*" means Board recognition that a patent application provides a proper constructive reduction to practice under 35 U.S.C. 102(g)(1).

Bd.R. 201 provides that "*constructive reduction to practice*" means a described and enabled anticipation under 35 U.S.C. 102(g)(1) in a patent application of the subject matter of a count.

Bd.R. 204(a) provides that a party may not submit evidence of its priority in addition to its accorded benefit unless it files a statement setting forth all bases on which the party intends to establish its entitlement to judgment on priority. Moreover, the priority statement must set forth, *inter alia*, the date and location of the party's earliest corroborated actual reduction to practice. Bd.R. 204(a)(3) further provides that, if a junior party fails to file a priority statement overcoming a senior party's accorded benefit, then judgment shall be entered against the junior party, absent a showing of good cause.

### C. Facts Believed to Have Been Overlooked by the Board

In view of the Decision on Motions, the Priority Order and the Board not entering judgment against Ni, the following facts (as a whole) are relevant to this request for reconsideration and are believed to have been overlooked by the Board:

* Regarding the priority benefit accorded to Ni with respect to Count 1 and Count 2, the Notice Declaring Interference (Paper No. 1) stated that Ni was accorded "none." *See*, Fact 1.

* Ni's Priority Statement, filed December 7, 2005, does not allege a date or location of a corroborated actual reduction to practice of Count 1 or Count 2. *See*, Facts 3-4. Therefore, in accordance with Bd.R. 204(a)(1), Ni cannot submit evidence of an actual reduction to practice to prove priority of either Count 1 or Count 2.

* Ni's Priority Statement states that party Ni "reserves the right" to rely on the filing date of any of the following applications as constructive reductions to practice "as detailed in NI SUBSTANTIVE MOTION 3":

U.S. Provisional Appl. No. 601040,846, filed March 17, 1997;
U.S. Provisional Appl. No. 601054,021, filed July 29, 1997;
U.S. Appl. No. 091042,583, filed March 17, 1998;
U.S. Provisional Appl. No. 601132,498, filed May 4, 1999;
U.S. Provisional Appl. No. 601133,238, filed May 7, 1999; and
U.S. Provisional Appl. No. 601148,939, filed August 13, 1999. [*See*, Fact 5].

* In the Decision on Motions, the Board denied Ni Substantive Motion 3, finding that none of the applications identified in Ni's Priority Statement constitutes a constructive reduction to practice of either Count 1 or Count 2. *See*, Fact 10-12. Therefore, in accordance with Bd.R. 204(a)(1), Ni cannot rely on any of these applications as a constructive reduction to practice to prove priority of either Count 1 or Count 2.

* Neither Ni's Priority Statement nor Ni Substantive Motion 3 asserted that Ni U.S. Application No. 09/565,009 ("the '009 application", from which Ni's involved patent issued), constitutes a constructive reduction to practice of either Count 1 or Count 2 or that Ni intended to

rely on the '009 application as a constructive reduction to practice for the purpose of proving priority with respect to either Count 1 or Count 2. *See*, Facts 6, 8.

* Ni's Priority Statement does not state that Ni intends to prove priority of invention with respect to either Count 1 or Count 2 by establishing corroborated reasonable diligence for the period prior to Adams' accorded benefit date of May 14, 1998, to the filing date of Ni's involved application, *i.e.*, May 4, 2000. *See*, Fact 7.

**D. Reconsideration and Entry of Judgment Against Ni Is Appropriate**

Although Ni filed a Priority Statement, it appears that the Board, in advancing the case to a priority contest (*see*, Decision on Motions and the Priority Order), has overlooked the fact that Ni's Priority Statement fails to overcome Adams' accorded benefit date of May 14, 1998.

In accordance with Bd.R. 204, Ni's Priority Statement was required to set forth all bases on which Ni intends to establish its entitlement to judgment on priority. Ni's Priority Statement does not allege an actual reduction to practice of Count 1 or Count 2. *See*, Fact 4. Ni's Priority Statement does not identify a legitimate constructive reduction to practice of Count 1 or Count 2. (*See* Decision on Motions; *see also* Fact 6). Therefore, Ni is procedurally barred from proving any reduction to practice of Count 1 or Count 2. Accordingly, judgment should be entered against Ni because Ni's Priority Statement fails to overcome Adams's accorded benefit.

**E. Even If Ni Has Met The Notice Requirements of Bd.R. 204, Entry Of Judgment Against Ni Is Appropriate, Absent A Showing Of Good Cause**

On page 6, the Priority Order states that Time Period 11 of the priority contest is to be completed by February 6, 2008. Facts 14-15.

As noted above, the Notice Declaring Interference did not recognize the involved Ni '009 application as constituting a constructive reduction to practice of Count 1 or Count 2. *See*, Fact

1. Moreover, Ni did not assert in its Priority Statement or in Ni Substantive Motion 3 that it considered the '009 application to constitute a constructive reduction to practice of Count 1 or Count 2 or that Ni intended to rely on it as such. *See*, Facts 6, 8. Nonetheless, even if Ni were to attempt to establish a date of invention with respect to either Count 1 or Count 2, Ni would be required to prove at least one year, eleven months, and twenty-two days of reasonable and corroborated diligence. *See*, Fact 2.

"The party chargeable with diligence must account for the entire period during which diligence is required." *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (evidence must be corroborated to be accorded weight); *see*, *also*, *Suh v. Hoefle*, 23 USPQ2d 1321, 1334, 1991 Pat. App. LEXIS 38, * 45-47 (BPAI 1991) (general testimony insufficient to prove reasonable diligence). *See also*, the requirements at paragraph 208.6 of the Standing Order. *See*, Fact 16.

In summary, Ni must prove by a preponderance of the evidence nearly two years of reasonable and corroborated diligence. *See*, *Singh v. Brake*, 317 F.3d 1334, 1340, 65 USPQ2d 1641, 1646 (Fed. Cir. 2003). It is noted that, in the context of Interference No. 105,240, Ni stated that it could not prevail on priority and requested entry of adverse judgment. *See*, Fact 19. The Ni claims involved in the '240 interference are identical to the Ni claims designated as corresponding to Count 1 in the present interference. *See*, Facts 17-18. If judgment is not entered against Ni for failing to file a priority statement alleging a date of invention sufficient to antedate Adams' accorded benefit date, then Ni should nonetheless be placed under an order to show good cause for litigating priority with respect to Count 1 and/or Count 2. The interests of justice will be served by knowing sooner, rather than later, whether Ni intends to contest priority in the instant interference.

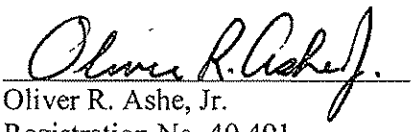
## V. Conclusion

In view of the above, Adams respectfully submits that, judgment should be entered against Ni with respect to Count 1 and Count 2 or, in the alternative, Ni should be placed under an Order to Show Cause why judgment on priority should not be entered against it.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

December 12, 2007



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## APPENDIX A

## EVIDENCE OR PAPERS OVERLOOKED OR MISAPPREHENDED BY THE BOARD

Notice Declaring Interference, filed August 31, 2005 (Paper No. 1).

Ni Substantive Motion 3, filed December 7, 2005 (Paper No. 37).

Ni's Priority Statement, filed December 7, 2005 (Paper No. 40).

Decisions on Motions, filed November 28, 2007 (Paper No. 107).

Order – Priority Times – Bd.R. 104(c), filed November 30, 2007 (Paper No. 108).

## APPENDIX B

### STATEMENT OF MATERIAL FACTS REPLIED UPON IN REQUEST FOR RECONSIDERATION

1. Regarding the priority benefit accorded to Ni with respect to Count 1 and Count 2, the Notice Declaring Interference stated: "Accorded Benefit: None". (Paper No. 1, p. 2).

2. In this Interference, Ni is junior party to Adams by one year, eleven months, and twenty-one days. (*See*, Paper No. 107, p. 5, lns. 20-22).

3. Ni's Priority Statement was filed December 7, 2005. (Paper No. 40, p. 4).

4. Ni's Priority Statement does not allege a date or location of a corroborated actual reduction to practice of the inventions of Count 1 or Count 2. (Paper No. 40, ¶ II, pp. 1-2).

5. Paragraph II of Ni's Priority Statement states, in part:

> Regardless of whether Party Ni is later able to provide a statement of the date and location of its earliest corroborated reduction to practice, Party Ni reserves the right to rely on the filing date of any earlier-filed application(s) to prove a constructive reduction to practice, *e.g.*, as detailed in NI SUBSTANTIVE MOTION 3 (to Change Benefit Accorded for the Subject Matter). Ni thus reserves the right to rely on the filing date of any of:
>
> - U.S. Provisional Appl. No. 601040,846, filed March 17, 1997;
> - U.S. Provisional Appl. No. 601054,021, filed July 29, 1997;
> - U.S. Appl. No. 091042,583, filed March 17, 1998;
> - U.S. Provisional Appl. No. 601132,498, filed May 4, 1999;
> - U.S. Provisional Appl. No. 601133,238, filed May 7, 1999; and
> - U.S. Provisional Appl. No. 601148,939, filed August 13, 1999. [Paper No. 40, ¶ II, p. 2].

6. Ni's Priority Statement does not allege that Ni U.S. Application No. 09/565,009 (from which Ni's involved patent issued), constitutes a constructive reduction to practice of either Count 1 or Count 2. (Paper No. 40, ¶ II, pp. 1-2).

7. Ni does not allege in its Priority Statement corroborated reasonable diligence for a period beginning from prior to Adams' accorded benefit of May 14, 1998, until Ni's accorded benefit date of May 4, 2000. (Paper No. 40, ¶ III, p. 2).

8. Ni Substantive Motion 3 does not allege that Ni U.S. Application No. 09/565,009 constitutes a constructive reduction to practice of either Count 1 or Count 2. (Paper No. 37).

9. The Decisions on Motions was filed November 28, 2007. (Paper No. 107, p. 1).

10. In the Decision on Motions, the Board denied Ni Substantive Motion 3 (Paper No. 37). (Paper No. 107, p. 26, lns. 25-26).

11. In the Decision on Motions, in denying Ni Substantive Motion 3, the Board found:

> In order to be entitled to benefit to an application for purpose of a count, [Ni] must show that the application provides a constructive reduction to practice of the invention under 35 U.S.C. §102(g). [Paper No. 107, p. 13, lns. 11-13].

12. In the Decision on Motions, the Board held that Ni was not entitled to the benefit of any earlier-filed applications with respect to Count 1 or Count 2. (Paper No. 107, p. 12, ln. 12 to p. 23, ln. 21).

13. The Order – Priority Times – Bd.R. 104(c) ("the Priority Order") was filed November 30, 2007. (Paper No. 109, p. 1).

14. The Priority Order states:

> 1. Time Period 11
>
> The junior party must:
>
> a. File and serve a motion on priority.
>
> b. Serve but not file evidence in support of the junior party priority case.
>
> If the junior party does not file a priority motion, the junior party must arrange a conference call to the administrative patent judge so that the appropriate action may be taken. [Paper No. 109, p. 2, lns. 11-18].

15. The Priority Order states:

> TIME PERIOD 11. . . February 6, 2008. [Paper No. 109, p. 6, Appendix – ORDER – RULE 123(a)].

16. Paragraph 208.6 of the Standing Order states:

> When diligence is an issue in priority, the priority motion must include as an appendix a diligence chart. The diligence chart must (1) list all days from the beginning of diligence through the end of diligence, (2) state what happened on each day, and (2) cite the page and line of the motion on which the listed day is discussed. . . . Every date gap in the diligence showing must be explained. The fact that there is a gap does not per se establish lack of reasonable diligence. The fact that there is no gap does not per se establish reasonable diligence. [SO ¶ 208.6].

17. In Interference No. 105,240, Count 1 is defined in the alternative by claim 21 of Ni's U.S. Patent No. 6,872,568 or claim 84 of Rauch Application 09/378,045 and Ni's claims 1-6, 8-19, 21-32, 34-45 and 47-52 are designated as corresponding to Count 1. (Redeclaration - Bd.R. 203(c), filed August 24, 2007, Paper No. 135, pp. 2-3).

18. In the current interference, Count 1 is defined in the alternative by claim 21 of Ni's U.S. Patent No. 6,872,568 or claim 134 of Adams Application 10/423,448 and Ni's claims 1-6, 8-19, 21-32, 34-45 and 47-52 are designated as corresponding to Count 1. (Declaration of Interference, filed August 31, 2005, Paper No. 1, p. 3).

19. Based on publicly available information, Ni appears to have stated that it "can not prevail on priority" and requested adverse judgment in Interference No. 105,240 with respect to the subject matter of Count 1. (Interference No. 105,240, "Judgment – Order to Show Cause – Bd.R. 202(d)" filed November 20, 2007, Paper No. 141).

## CERTIFICATE OF FILING

The undersigned certifies that a copy of the paper entitled **"ADAMS REQUEST FOR RECONSIDERATION"** was filed this 12th day of December, 2007, by Federal Express overnight delivery service, to:

The Board of Patent Appeals and Interferences
Madison Building East, 9th Floor
600 Dulany Street
Alexandria, VA 22314
Tel.: 571-272-9797
Fax: 571-273-0042
E-mail: BoxInterferences@USPTO.GOV

December 12, 2007

Oliver R. Ashe, Jr.

## CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the paper entitled **"ADAMS REQUEST FOR RECONSIDERATION"** was served this 12th day of December, 2007, by Federal Express overnight delivery service, on the Attorney of Record for the party Ni:

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A copy of the same paper was served this 12th day of December, 2007, by Federal Express overnight delivery service, on the Attorney of Record for the party Rauch:

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Fax: 310-788-3399
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December 12, 2007

Oliver R. Ashe, Jr.

# EXHIBIT 16

THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY

# EXHIBIT 17

----- Original Message -----
**From:** "Pfeffer, Antony" [APfeffer@kenyon.com]
**Sent:** 05/20/2008 04:45 PM AST
**To:** Elizabeth Weiswasser
**Cc:** Vern Winters; "DeLucia, Richard" <RDelucia@kenyon.com>
**Subject:** RE: HGS v Genentech

FROM RICHARD L. DELUCIA:

Elizabeth,

Thank you for the OED letter. Upon evaluation of the letter, we decline to delete the issues you have raised from the scope of the 146 action. We do however plan to continue to evaluate the matter in light of discovery we take during the action and in light of any additional information that you provide to us.

Thanks,

Rich

---

**From:** Elizabeth.Weiswasser@weil.com [mailto:Elizabeth.Weiswasser@weil.com]
**Sent:** Monday, May 19, 2008 6:28 PM
**To:** DeLucia, Richard
**Cc:** Pfeffer, Antony; vern.winters@weil.com
**Subject:** Re: HGS v Genentech

Thanks for the update, Rich.

---

----- Original Message -----
**From:** "DeLucia, Richard" [RDelucia@kenyon.com]
**Sent:** 05/19/2008 06:12 PM AST
**To:** Elizabeth Weiswasser
**Cc:** "Pfeffer, Antony" <APfeffer@kenyon.com>; Vern Winters
**Subject:** RE: HGS v Genentech

I was just about to e-mail you. I am working on the issue you raised and fully expect to be able to respond tomorrow afternoon. Thanks Rich

---

**From:** Elizabeth.Weiswasser@weil.com [mailto:Elizabeth.Weiswasser@weil.com]
**Sent:** Mon 5/19/2008 6:06 PM

**To:** DeLucia, Richard
**Cc:** Pfeffer, Antony; Vern Winters
**Subject:** RE: HGS v Genentech

Rich -- checking in on this to see where it stands; I just left you a voice message in the office as well. Looking forward to hearing from you. Liz

Elizabeth Stotland Weiswasser
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(c) (646) 842-0505
elizabeth.weiswasser@weil.com

**"DeLucia, Richard" <RDelucia@kenyon.com>**

05/16/2008 07:08 AM

To <Elizabeth.Weiswasser@weil.com>
cc "Vern Winters" <vern.winters@weil.com>, "Pfeffer, Antony" <APfeffer@kenyon.com>
Subject RE: HGS v Genentech

We are working on the response to the sanctions claims you and should be able to respond Monday. Thanks Rich

---

**From:** Elizabeth.Weiswasser@weil.com [mailto:Elizabeth.Weiswasser@weil.com]
**Sent:** Thu 5/15/2008 6:56 PM
**To:** DeLucia, Richard
**Cc:** Vern Winters
**Subject:** HGS v Genentech

Rich -- following up on Vern's note below, do you have an answer whether your client will agree to extend the stip through May 30? Also when will you advise of HGS' position on the sanctions claims per your correspondence with Vern? We look forward to your response. Liz

**********

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----- Original Message -----
From: vern.winters@weil.com <vern.winters@weil.com>
To: DeLucia, Richard
Cc: Elizabeth.Weiswasser@weil.com <Elizabeth.Weiswasser@weil.com>
Sent: Wed May 14 10:44:22 2008
Subject: HGS v. Genentech

Rich--thank you for the interim extension through next Wednesday in light of the Court's Order yesterday and for other reasons. Both Liz Weiswasser and I will be travelling on other separate matters for several days before then, including (for both of us) weekend travel. If you could confirm that HGS could grant the extension to and including May 30, 2008, we would appreciate it. We acknowledge that you are probably busy just now, but if you could let us know, that would help. Vern.

**********

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w: www.weil.com

< END >

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# EXHIBIT 18

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| HUMAN GENOME SCIENCES, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | Civil Action No. 07-780-SLR |
| v. | ) | |
| | ) | |
| AMGEN INC. & IMMUNEX CORP., | ) | |
| | ) | |
| Defendant. | ) | |

**HGS' MOTION FOR RECONSIDERATION**
**AND MODIFICATION OF ORDER**

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John G. Day (I.D. #2403)
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Dated: May 23, 2008

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## TABLE OF AUTHORITIES

CASES

## INTRODUCTION

In accordance with D. Del. L.R. 7.1.5, and pursuant to Fed. R. Civ. P. 59, Human Genome Sciences ("HGS") submits this request for rehearing, reconsideration, and modification of the Court's May 12, 2008 Order (D.I. 28) and Memorandum Opinion (D.I. 27). Although HGS recognizes that the relief it seeks here is infrequently granted, HGS respectfully requests the Court's indulgence and reconsideration on this issue, and requests modification of the Court's May 12 Order in view of the of the complexity of the issues presented to the Court and the nature of the Court's ruling.

In its complaint, HGS listed numerous decisions of the Board that it was challenging. (*See e.g.*, D.I. 1 at ¶ 14).[1] In its Order, the Court dismissed HGS' § 146 action in its entirety for reasons related to review of the issue of "priority" of invention (*i.e.*, the date that the parties made the invention and which party made the invention first). However, in dismissing the action in its entirety, the Court has denied HGS any review under § 146 of the Board's decisions from the substantive motions phase that were fully explored, briefed and argued by the parties; decisions which are at the heart of HGS's § 146 action.[2] Because § 146 unequivocally grants any party dissatisfied with a decision of the Board the remedy of review by a District Court, the Board's decisions in the substantive motions phase, which are not "priority" decisions, fall squarely within the Court's subject matter jurisdiction under § 146. Such review is not discretionary. *See* 35 U.S.C. § 146.

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1 There are two other related § 146 actions currently pending before the Court, Civil Action Nos. 07-526 and 08-166. An additional interference, Interference No. 105,380, is still pending at the PTO awaiting a final decision of the Board in the priority phase.

2 As discussed below, an interference has both a substantive motions phase and a priority phase. In the underlying interference, the substantive motions phase was fully briefed.

In moving to dismiss, Immunex argued that review of the Board's decisions had been rendered moot and that interference estoppel precluded review. These arguments were soundly rejected by the Court. However, Immunex never argued that the Court otherwise lacked subject matter jurisdiction with respect to the underlying decisions of the Board. Indeed, the parties never briefed that issue.[3]

In contrast to the issues argued by the parties with respect to the motion to dismiss, and as a central reason for its dismissal of this action, the Court expressed concern that allowing this action to proceed would "constitute an effective usurpation of the Board's original jurisdiction to determine priority." (D.I. 27). The Court further voiced the view that "HGS presented the Board little more than conclusory arguments" on the issue of priority. HGS respectfully submits that its briefing on the issues decided by the Board in its decisions during the substantive motions phase are within the jurisdiction of the Court under § 146 and the applicable caselaw. With respect to the Court's concern that the Board was unable to "specifically define" the priority phase (see Memorandum Opinion, p. 15), it is clear that as a matter of incontrovertible fact, the Board fully and concretely defined the priority phase based on the Parties' briefings, arguments and evidentiary submissions during the substantive motions phase.

Further, the question of the adequacy of HGS' submissions to the Board with respect to the very decisions on which HGS seeks review is not related to the existence of jurisdiction, but rather goes to the merits of this action under § 146. While discretion exists for the Court to consider issues *not* raised in an interference, there is nothing in the caselaw to support the

---

[3] In seeking a modification of the Court's order HGS is mindful that a motion for reconsideration is not a vehicle to merely reargue a prior motion. However, the grounds for the dismissal of this action, as set forth in the Memorandum Opinion, were not briefed by the parties in the motion papers. Accordingly, reconsideration and modification of the Order is proper as the Court has "made a decision outside the adversarial issues presented to the Court by the parties." *Tinney v. Geneseo Communs., Inc.*, 502 F. Supp. 2d 409, 415 (D.Del. 2007) (quoting *Brambles USA, Inc. v. Blocker*, 735 F. Supp. 1239, 1241 (D. Del. 1990)).

proposition that a Court has discretion not to review issues which were raised and (as in this case) actually decided by the Board. See Section II *infra.* Finally, the Court's concerns related to the Board's original jurisdiction to determine priority can be fully addressed without dismissal of this action in its entirety, thereby allowing the Court to retain jurisdiction over those issues that were fully briefed by the parties and decided by the Board.

To address this Court's concerns, HGS proposes a modified order that would limit review in this case to the decisions made by the Board during the fully-briefed substantive motions phase of the underlying interference. This proposed order eliminates any issues of usurpation of jurisdiction. Under the proposed order, the Court would review the Board's decisions rendered during the substantive motion phase, and thereafter decide whether to hear the priority case, remand to the Board for consideration in a priority phase of the interference (if, for example, the Court changed the accorded benefit dates of the parties), or affirm the Board's decisions from the substantive motion phase, thereby potentially eliminating the need for the Court to decide priority at all in this § 146 action.

## I. The Decisions of the Board in the Substantive Motions Phase of the Interference Defined the Priority Dispute for the Priority Phase

Under the current rules, a patent interference is normally divided into two phases. The first phase is referred to as the "substantive motions phase." In this phase, the Board considers issues such as the scope of the interference, what patent claims are involved in the interference, the dates of benefit that each party will be accorded (establishing their respective dates of constructive reduction to practice), and certain issues regarding the patentability of the parties' claims. The decisions made by the Board on the motions filed during the "substantive motions phase" set the ground rules for the later priority dispute. It is in this second phase, the priority phase, that the Board determines the ultimate issue of priority by reviewing arguments and

evidence related to the dates of conception, actual reduction to practice, and the reasonable diligence from conception to the earliest reduction to practice. The evidence that must be offered and arguments that must be made by the parties during the priority phase are dictated by the decisions that are made by the Board in the substantive motions phase. Issues decided during the substantive motions phase are not subject to reconsideration or further briefing in the priority phase.

As part of the underlying '240 interference, HGS and Immunex filed numerous motions during the substantive motions phase. For example, HGS filed a motion to change the count, a motion regarding entitlement to benefit of the filing of earlier patent applications, a motion for invalidity of Immunex's involved claims, and a motion for entitlement to obtain certain discovery from third parties. Immunex filed assorted motions as well, including a motion seeking benefit of earlier filed patent applications. These motions were fully briefed, declarations were filed, depositions of the declarants were taken, the motions were argued before the Board, and on July 26, 2007, the Board issued a 73-page opinion setting forth its decisions on these motions. The Board's decisions in the substantive motions phase defined the framework within which the parties would have to work during the priority phase. HGS is dissatisfied with the decisions rendered by the Board during the substantive motions phase, and has conceded priority under the specifically-defined priority contest dictated by the Board in order to seek review of the underlying decisions. Although HGS believes that it will ultimately prevail on the issue of priority if the priority dispute is properly framed, that issue need not be decided at this time.

## II. HGS Has a Statutory Right, Pursuant to 35 U.S.C. § 146, to Obtain District Court Review of the Decisions of the Board Made During the Substantive Motions Phase of the Interference

It is undisputed that HGS is dissatisfied with certain decisions of the Board of Patent Appeals and Interferences, all of which are specifically identified in the complaint. 35 U.S.C. § 146 provides: "Any party to an interference *dissatisfied with the decision* of the Board of Patent Appeals and Interferences on the interference may have remedy by civil action." (emphasis added). Thus, this Court plainly has subject matter jurisdiction over all decisions actually rendered by the Board. *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994). In fact, Immunex never even argued that this Court lacked authority to review the decisions of the Board during the substantive motions phase, but instead argued that any such review was moot or barred by interference estoppel.

An actual decision of the Board is unquestionably reviewable under § 146. All that is necessary for an issue to be reviewed under § 146 is that the issue be raised through a motion (or similar procedure), *i.e.*, it is not even necessary that the Board ultimately render a decision on an issue. *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994); *see also*, *General Instrument Corp. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 214 (Fed. Cir. 1993). Often in § 146 actions the question arises as to whether the Court should consider issues which had not been raised below. With respect to those issues never raised below, it is still within the court's discretion to consider them. *See Conservolite*, 21 F.3d at 1102 ("Under appropriate circumstances, a district court may exercise its discretion and admit testimony on issues even though they were not raised before the Board.") While discretion exists for the Court to consider issues *not* raised in an interference, there is nothing in the caselaw to support the proposition that a Court has discretion not to review issues which were raised and (as in this case) actually decided by the Board.

The Court, however, expressed concern that proceeding with the statutorily mandated review could usurp the Board's original jurisdiction on *priority* phase issues, leaving room for mischief.[4] In particular, the Court indicated that the Board may not have been given a full and fair opportunity to determine priority because HGS allegedly presented the Board with little more than conclusory arguments that did not allow the Board to specifically define the scope of the dispute. HGS disagrees that its arguments before the Board were conclusory or that the Board was unable to specifically define the scope of the dispute. HGS submitted detailed substantive evidence, briefing and argument in support of its substantive motions and in opposition to Immunex's substantive motions. Included in this support were hundreds of pages of briefing, deposition transcripts, expert declarations, and numerous exhibits. *See* Exhibit A to Declaration of A. Antony Pfeffer.

Because the scope of the briefing at the Board was not the focus of the parties or the Court in addressing Immunex's motion to dismiss, HGS did not submit evidence of its extensive efforts before the Board. Without now burdening the Court with the submission of all of that evidence, HGS submits as an example its Motion for Benefit, which provides detailed arguments regarding how HGS' earlier applications, including the earliest HGS application, described and enabled the invention at issue in the interference. In this motion HGS cites expert declarations and numerous technical articles supporting its position. *See* Exhibit B to Declaration of A. Antony Pfeffer. The Board heard oral argument on this motion and rendered a final decision on the issue of benefit, as well as other issues raised by HGS and Immunex during the substantive motions phase.

---

[4] HGS respectfully objects to any implication that it was engaged in mischief. HGS strenuously attempted to receive satisfaction from the Board. Upon the priority contest being defined in an extremely unfavorable light, HGS took steps to facilitate review of the decisions made during the substantive motions phase in as swift and efficient a means as possible.

The issue of whether HGS presented sufficient evidence to prevail before the Board is not a jurisdictional matter. Furthermore, by dismissing this case for lack of subject matter jurisdiction, the Court cut off any opportunity for HGS to seek review of the Board's decisions on the substantive motions, including specific rulings by the Board concerning the content of HGS' prior patent applications, which the Court referred to and appeared to rely on in dismissing HGS' complaint. (D.I. 27 at 15). In conformance with the ideals of equity and due process, HGS should be provided the opportunity to present evidence and argument to this Court concerning the issues that were decided by the Board during the substantive motions phase of the underlying interference, as expressly provided in 35 U.S.C. § 146.

## III. Following Review of the Board's Decisions During the Substantive Motions Phase the Court Can Determine Whether to Decide the Issue of Priority or Remand That Issue to the Board

The Board's decisions rendered in the substantive motions phase fully defined the priority battle, the scope of the interference and the parties various dates for conception and reduction to practice. The Board would not have entered the priority phase without having fully defined the priority dispute. If this Court affirms all of the Board's decisions on the substantive motions, it can affirm the Board's award of priority to Immunex. However, if those decisions are reversed or otherwise modified, a new priority case would be defined.

HGS requested that the Board enter adverse judgment on the priority phase issues because the decisions of the Board in the substantive motions phase made it unlikely (at best) that HGS could defeat Immunex in the priority phase. In the decisions in the substantive motions phase, Immunex was awarded the earliest date for a constructive reduction to practice. Based on the decision, HGS would have been forced to antedate Immunex's date with an earlier conception and show reasonable "diligence" in working on the invention from this conception for a period of more than three years. In view of the legal requirements for demonstrating

reasonable diligence, establishing reasonable diligence for three-plus-year period is, to be charitable, an extremely difficult endeavor. Accordingly, HGS conceded priority under the specific factual scenario framed by the Board's decisions in the substantive motions phase.

However, it is HGS' belief that following review of the Board's decisions by this Court, the priority phase contest will be redefined in the manner HGS urged before the Board. In this scenario, HGS would be awarded the earliest date for a constructive reduction to practice and Immunex would be forced to antedate There was never an opportunity for this priority case to be evaluated by the Board due to the decisions in the substantive motion phase. Moreover, the Court would not be usurping the Board's jurisdiction by analyzing this priority contest in the first instance.

Nevertheless, to address the Court's concerns regarding encroachment on the Board's original jurisdiction, HGS notes that the Court need not decide the priority issues during this action. The Court, in its discretion, can remand the issue of priority to the Board if the Board's decisions on substantive motions are reversed. *Enzo Therapeutics v. Yeda Research & Dev. Co.*, 477 F. Supp. 2d 699 (E.D. Va. 2007) (remanding case to the board); *Bio-Technology Gen. Corp. v. Novo Nordisk A/S*, No. 02-235-SLR, 2004 U.S. Dist. LEXIS 14959 (D. Del. Aug. 3, 2004) (reversing, *inter alia*, Board's benefit decision and remanding interference to the Board); *Plumley v. Mockett*, No. 98-6117-GHK (Ex), 1999 U.S. Dist. LEXIS 23308 (C.D. Cal. Jun. 4, 1999) (setting aside the Board's derivation decision and remanding priority case to the Board); *see also, Dow Chem. Co. v. Exxon Chem. Patents*, No. 96-160-SLR, 1998 U.S. Dist. LEXIS 5340 (D. Del. Mar. 24, 1998) (vacating the Board's final judgment and remanding); *KLA Instruments Corp. v. Orbot Inc.*, No. 92-20676-JW, 1997 U.S. Dist. LEXIS 24065 (N.D. Cal. May 14, 1997) (same); *Kochler v. Mustonen*, 774 F. Supp. 641 (D.D.C. 1991) (same). And, as

discussed above, if the Board's decisions are affirmed, then priority will not be an issue since HGS has already conceded priority under that particular set of facts. Under no circumstance would dismissal be required to protect the original jurisdiction of the Board regarding priority.

The proposed modified order submitted herewith addresses all of the Court's concerns regarding the ability of the Board to evaluate priority issues in the first instance, while maintaining HGS' statutory right to a review of the decisions from the substantive motion phase in this interference. Rather than dismiss HGS' complaint in its entirety at this time, the Court should review the fully-briefed decisions of the board and determine the appropriate course of action (remand, affirmance, or evaluation of priority) at a more appropriate time.

## CONCLUSION

HGS respectfully requests reargument and reconsideration of the Court's Order granting Immunex's motion to dismiss this case (D.I. 28) and Memorandum Opinion (D.I. 27). HGS respectfully requests that the Court modify its order in the form of the attached proposed order. This order addresses the Court's concern with respect to the issue of priority. This order balances HGS' statutory right to judicial review with the concerns of the Court regarding evaluation of priority without briefing to the Board.

ASHBY & GEDDES

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Dated: May 23, 2008

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| HUMAN GENOME SCIENCES, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | Civil Action No. 07-780 (SLR) |
| v. | ) | |
| | ) | |
| AMGEN INC. & IMMUNEX CORP., | ) | |
| | ) | |
| Defendants. | ) | |

**ORDER MODIFYING MAY 9, 2008 ORDER**

AND NOW, on this ____ day of _____ 2008, upon consideration of the submissions of the parties the Order dated May 9, 2008 (D.I. 28) is hereby modified as follows:

Defendant's Motion to Dismiss (D.I. 8) is hereby denied;

The Order dated May 9, 2008 (D.I. 28) is vacated;

Review under 35 U.S.C. § 146 of the various decisions of the Board set forth in paragraph 14 of the Complaint (D.I. 1) shall proceed in this action;

Unless this Order is modified sua sponte or by motion, the issue of priority will not be addressed until the Court has ruled on the decisions set forth in paragraph 14 of the Complaint. After the Court has ruled on those decisions, the Court will determine whether to decide the ultimate issue of priority or remand that issue to the Board of Patent Appeals and Interference of the United States Patent and Trademark Office.

SO ORDERED this _____ day of _____, 2008.

_____
United States District Judge